FEDERAL REGISTER

Vol. 86 Monday

No. 245 December 27, 2021

Pages 73105–73590

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: 86 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	**202–512–1800**
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. 86, No. 245

Monday, December 27, 2021

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.

Rules and Regulations

Federal Register
Vol. 86, No. 245
Monday, December 27, 2021

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 539

Weapons of Mass Destruction Trade Control Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is amending the Weapons of Mass Destruction Trade Control Regulations to add a June 28, 2005 Executive order as an authority, remove the appendix to the part, and modify three definitions referencing the appendix.

DATES: This rule is effective December 27, 2021.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *www.treasury.gov/ofac.*

Background

On February 23, 1999, OFAC issued the Weapons of Mass Destruction Trade Control Regulations, 31 CFR part 539 (64 FR 8715, February 23, 1999) (the ''Regulations''), to implement Executive Order (E.O.) 12938 of November 14, 1994, ''Proliferation of Weapons of Mass Destruction'' (59 FR 59099, November 16, 1994), as amended by E.O. 13094 of July 28, 1998, ''Proliferation of Weapons of Mass Destruction'' (63 FR 40803, July 30, 1998). Since that time, OFAC has amended the Regulations to remove two names from appendix I to the Regulations (66 FR 57371, November 15, 2001).

Appendix I to the Regulations lists the names of foreign persons who are determined by the Secretary of State pursuant to section 4(a) of E.O. 12938, as amended by E.O. 13094, to have materially contributed or attempted to contribute materially to the efforts of a foreign country, project, or entity of proliferation concern to use, acquire, design, develop, produce, or stockpile weapons of mass destruction or missiles capable of delivering such weapons, and who are subject to import measures authorized in E.O. 12938, as amended. Although appendix I to the Regulations has not been updated since November 15, 2001, the names of persons subject to the import measures authorized in E.O. 12938, as amended, are published in the **Federal Register** and maintained on the Department of State's website. All persons currently listed in appendix I to the Regulations have been determined by the Department of State to no longer be subject to the import measures authorized in E.O. 12938, as amended, and the Department of State has published these determinations in the **Federal Register**.[1] The list maintained on the Department of State's website has been updated to reflect that these persons are no longer subject to sanctions under E.O. 12938, as amended.

In addition, since November 15, 2001, E.O. 12938, as amended, has been further amended. On June 28, 2005, the President, invoking the authority of, inter alia, the International Emergency Economic Powers Act (50 U.S.C. 1701–1706), issued E.O. 13382, ''Blocking Property of Weapons of Mass Destruction Proliferators and Their Supporters'' (70 FR 38567, July 1, 2005), effective at 12:01 a.m. eastern daylight time on June 29, 2005. E.O. 13382 blocks the property and interests in property of certain persons and is implemented in the Weapons of Mass Destruction Proliferators Sanctions Regulations, 31 CFR part 544. In addition, E.O. 13382 further amended section 4(a) of E.O. 12938 to add the Secretary of the Treasury as a consultative party and expand the foreign persons who could be subject to the import measures of E.O. 12938, as amended, to the following: Foreign persons determined by the Secretary of State, in consultation with the Secretary of the Treasury, to have engaged, or attempted to engage, in activities or transactions that have materially contributed to, or pose a risk of materially contributing to, the proliferation of weapons of mass destruction or their means of delivery (including missiles capable of delivering such weapons), including any efforts to manufacture, acquire, possess, develop, transport, transfer, or use such items, by any person or foreign country of proliferation concern. Accordingly, OFAC is adding E.O. 13382 as an authority to the Regulations.

In light of the further amendment to section 4(a) of E.O. 12938, the removal of all persons from appendix I, and the Department of State's regular practice of publishing in the **Federal Register** notices of the determinations of the Secretary of State, in consultation with the Secretary of the Treasury, that a person meets or no longer meets the criteria of section 4(a) of E.O. 12938, as amended, OFAC is also now removing appendix I from the Regulations.

OFAC is also amending the definitions in §§ 539.301, 539.302, and 539.304 in the Regulations to reflect the removal of appendix I and making technical edits to the authority citation to conform to **Federal Register** guidance.

Public Participation

Because the Regulations involve a foreign affairs function, the provisions of E.O. 12866 of September 30, 1993, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

The collections of information related to the Regulations are contained in 31 CFR part 501 (the ''Reporting, Procedures and Penalties Regulations'').

[1] Baltic State Technical University was removed on February 4, 2010 (74 FR 5836); Europlace 2000, Grafit, MOSO Company, and NKIET were removed on April 1, 2004 (69 FR 17262); Glakosmos was removed on March 10, 2010 (75 FR 11223); D. Mendelyev University of Chemical Technology of Russia and Moscow Aviation Institute (MAI) were removed on May 21, 2010 (75 FR 28672).

Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget under control number 1505–0164. 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.

List of Subjects in 31 CFR Part 539

Administrative practice and procedure, Arms and munitions, Foreign Trade, Imports, Penalties, Reporting and recordkeeping requirements, Sanctions, Services, Weapons of mass destruction.

For the reasons set forth in the preamble, OFAC amends 31 CFR part 539 as follows:

PART 539—WEAPONS OF MASS DESTRUCTION TRADE CONTROL REGULATIONS

■ 1. The authority citation for part 539 is revised to read as follows:

Authority: 3 U.S.C. 301; 22 U.S.C. 2751–2799aa–2; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13094, 63 FR 40803, 3 CFR, 1998 Comp., p. 200; E.O. 13382, 70 FR 38567, 3 CFR, 2005 Comp., p. 170.

Subpart C—General Definitions

■ 2. Revise § 539.301 to read as follows:

§ 539.301 Designated foreign person.

The term *designated foreign person* means any person determined by the Secretary of State, in consultation with the Secretary of the Treasury, to be subject to import measures pursuant to section 4(a) of Executive Order (E.O.) 12938 of November 14, 1994, as amended by E.O. 13094 of July 28, 1998 and E.O. 13382 of June 28, 2005.

Note 1 to § 539.301. The Department of State publishes in the **Federal Register** the names of persons determined to be subject to import measures pursuant to section 4(a) of E.O. 12938, as amended, and maintains a list of such persons accessible through the following page on the Department of State's website: *https://www.state.gov/key-topics-bureau-of-international-security-and-nonproliferation/nonproliferation-sanctions/.*

§ 539.302 [Amended]

■ 3. In § 539.302, remove the last sentence of the section.

§ 539.304 [Amended]

■ 4. Amend § 539.304 as follows:
■ a. Remove ''person listed in appendix I to this part'' everywhere it appears and add in its place ''designated foreign person.''
■ b. Remove ''entities listed in appendix I to this part'' and add in its place ''entities that are designated foreign persons.''

Appendix I to Part 539 [Removed]

■ 5. Remove appendix I.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2021–27868 Filed 12–23–21; 8:45 am]

BILLING CODE 4810–AL–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2020–0079; FRL–9291–01–R9]

Air Plan Approval; California; San Joaquin Valley Unified Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to partially approve a revision to the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD) portion of the California State Implementation Plan (SIP). This revision concerns emissions of oxides of nitrogen (NO_X) and fine particulate matter ($PM_{2.5}$) from off-road diesel agricultural vehicles and equipment. We are approving portions of a local measure to reduce emissions from these sources under the Clean Air Act (CAA or the Act) and deferring action on the remaining portions of this measure.

DATES: This rule is effective January 26, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2020–0079. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information 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 *http://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: Rebecca Newhouse, EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105, (415) 972–3004, *newhouse.rebecca@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

Table of Contents

I. Background

On March 24, 2020 (85 FR 16588), the EPA proposed to approve the following measure, submitted by the California Air Resources Board (CARB), into the California SIP.

Local agency	Resolution No.	Measure title	Adopted	Submitted
CARB	19–26	''San Joaquin Valley Agricultural Equipment Incentive Measure,'' as amended by ''Additional Clarifying Information for the San Joaquin Valley Agricultural Equipment Incentive Measure.''	12/12/19	02/11/20

We proposed to approve the San Joaquin Valley Agricultural Equipment Incentive Measure, as amended (hereafter ''Valley Incentive Measure''), based on a determination that it satisfies the applicable CAA requirements for approval of voluntary measures for SIP emission reduction credit. Our proposal was based on our evaluation of the documents provided in the SIP submission, including the measure itself (*i.e.,* the State commitments set forth on

pages 7–12 of CARB Resolution 19–26, as amended by the ''Additional Clarifying Information for the San Joaquin Valley Agricultural Equipment Incentive Measure'') and CARB's analysis of the measure in a document entitled ''San Joaquin Valley Agricultural Equipment Incentive Measure—Quantifying the Funded Emission Reductions from Moyer, NRCS, and FARMER Programs to Achieve SIP Credit,'' Release Date: November 8, 2019 (hereafter ''Demonstration''). Our proposed rule and associated technical support document (TSD) [1] contain more information about the SIP submission and our evaluation thereof.

On March 27, 2020 (85 FR 17382), as part of the EPA's proposal to approve most elements of California's attainment plan for the 2006 $PM_{2.5}$ NAAQS in the San Joaquin Valley (''2006 NAAQS Plan''), the EPA proposed to credit the Valley Incentive Measure with specific amounts of NO_X and $PM_{2.5}$ emission reductions toward the State's aggregate emission reduction commitments for 2024 in this plan. Specifically, the EPA proposed to find that the Valley Incentive Measure would achieve 5.9 tons per day (tpd) of NO_X reductions and 0.3 tpd of direct $PM_{2.5}$ reductions by 2024, as part of the State's control strategy for attaining the 2006 $PM_{2.5}$ NAAQS in the San Joaquin Valley by December 31, 2024.[2] We did not, however, finalize this element of our March 27, 2020 proposal because, as of the date of our final action on the 2006 NAAQS Plan, we had not yet approved the Valley Incentive Measure into the SIP.[3]

On November 24, 2020, CARB submitted technical clarifications and corrections to the Valley Incentive Measure that clarify, among other things, CARB's commitment to make certain documents concerning the incentive projects implemented to achieve emission reductions available to the public upon request. CARB adopted these technical clarifications and corrections to the measure by Executive Order S–20–031 (November 23, 2020).[4] These technical clarifications and corrections to the Valley Incentive Measure incorporate all amendments contained in the ''Additional Clarifying Information for the San Joaquin Valley Agricultural Equipment Incentive Measure.'' We refer to the executive order adopting these technical clarifications and corrections as the ''Technical Corrections Document.''

On October 6, 2021, CARB submitted an additional clarification to the Valley Incentive Measure stating that CARB's commitments for ''aggregated emissions reductions and pieces of agricultural equipment'' in the measure may be achieved through any combination of the referenced incentive programs. CARB adopted this clarification to the measure by Executive Order S–21–018 (October 6, 2021).[5] CARB's submittal letter explains that this clarification to the Valley Incentive Measure makes the commitment ''severable'' so that the EPA ''may address the associated emissions reductions and pieces of agricultural equipment from the incentive programs individually as needed.'' [6] We refer to the executive order adopting this clarification as the ''2021 Clarification Document.''

The 2006 NAAQS Plan is contained within an integrated $PM_{2.5}$ attainment plan submitted by CARB on May 10, 2019, that also contains, inter alia, California's Serious area attainment plan for the 2012 annual $PM_{2.5}$ NAAQS in the San Joaquin Valley (the ''2012 NAAQS Plan'').[7] For purposes of this action we refer to the 2006 NAAQS Plan and 2012 NAAQS Plan together as the ''SJV $PM_{2.5}$ Plan,'' and to the portion of the SJV $PM_{2.5}$ Plan that the SJVUAPCD developed and adopted as the ''2018 $PM_{2.5}$ Plan.'' The SJV $PM_{2.5}$ Plan lists the Valley Incentive Measure as one of several defined measures that CARB intended to adopt in order to fulfill, in part, its aggregate tonnage commitments in the SJV $PM_{2.5}$ Plan. Specifically, the 2006 NAAQS Plan relies on the 2024 tonnage commitment in the Valley Incentive Measure to achieve a portion of the emission reductions necessary for attainment of the 2006 $PM_{2.5}$ NAAQS by the end of 2024,[8] and the 2012 NAAQS Plan relies on the 2025 tonnage commitment in the Valley Incentive Measure to achieve a portion of the emission reductions necessary for attainment of the 2012 $PM_{2.5}$ NAAQS by the end of 2025.[9]

II. Summary of Final Action and Rationale

We are taking final action to approve into the California SIP specific portions of the Valley Incentive Measure, as amended and clarified by the Technical Corrections Document and the 2021 Clarification Document, based on our conclusion that these portions of the measure satisfy CAA requirements for approval. Our March 24, 2020 proposed rule (85 FR 16588), the associated TSD, and our responses to comments in this final rule provide our rationale for finding that these portions of the measure are enforceable and satisfy CAA requirements for SIP approval, as interpreted in the EPA's guidance. Upon our approval of these portions of the Valley Incentive Measure into the SIP, they become enforceable under the CAA and creditable for SIP purposes. Accordingly, we are also taking final action to credit these portions of the Valley Incentive Measure with specific amounts of NO_X and direct $PM_{2.5}$ emission reductions toward the 2024 aggregate tonnage commitments in the 2006 NAAQS Plan, which we

[1] EPA Region IX, ''Technical Support Document for EPA's Rulemaking for the California State Implementation Plan, California Air Resources Board Resolution 19–26, San Joaquin Valley Agricultural Equipment Incentive Measure,'' February 2020 (hereafter ''TSD'').

[2] 85 FR 17382, 17412.

[3] 85 FR 44192, 44204 (July 22, 2020).

[4] Letter dated November 23, 2020, from Richard W. Corey, Executive Officer, CARB, to John W. Busterud, Regional Administrator, EPA Region IX (transmitting, inter alia, CARB Executive Order S–20–031, ''Adoption and Submittal of Technical Clarifications and Typographical Error Corrections to the San Joaquin Valley Agricultural Equipment Incentive Measure,'' November 23, 2020 (hereafter ''Technical Corrections Document'')).

[5] Letter dated October 6, 2021, from Richard W. Corey, Executive Officer, CARB, to Deborah Jordan, Acting Regional Administrator, EPA Region IX (transmitting CARB Executive Order S–21–018, ''Adoption and Submittal of Commitment Clarifications to the San Joaquin Valley Agricultural Equipment Incentive Measure,'' October 6, 2021 (hereafter ''2021 Clarification Document'')).

[6] CARB submitted the 2021 Clarification Document in response to the EPA's email dated June 2, 2021, which contained two PDF attachments identifying, in redline and strikeouts, suggested edits to the Valley Incentive Measure to remove all references to NRCS projects and associated commitments. Email dated June 2, 2021, from Rebecca Newhouse (EPA) to Sylvia Vanderspek (CARB), RE: ''SJV ag tractor incentive measure'' (including attachments).

[7] Letter dated May 9, 2019, from Richard Corey, Executive Officer, CARB, to Mike Stoker, Regional Administrator, EPA Region 9 (transmitting the ''2018 Plan for the 1997, 2006, and 2012 $PM_{2.5}$ Standards'' (''2018 $PM_{2.5}$ Plan'') and the ''San Joaquin Valley Supplement to the 2016 State Strategy for the State Implementation Plan'' (''Valley State SIP Strategy'')). The SJVUAPCD developed and adopted the 2018 $PM_{2.5}$ Plan, and CARB developed and adopted the Valley State SIP Strategy. 85 FR 44192, 44193.

[8] 2018 $PM_{2.5}$ Plan, Chapter 4, Section 4.4 (''CARB Emission Reduction Commitment for the San Joaquin Valley'') and Valley State SIP Strategy, Chapter 3 (''Supplemental State Commitment from the Proposed State Measures for the Valley''). See also 85 FR 17415–17416 (March 27, 2020) (proposed rule to approve relevant portions of SJV $PM_{2.5}$ Plan for 2006 $PM_{2.5}$ NAAQS purposes, discussing plan's reliance on San Joaquin Valley Agricultural Incentive Measure) and 85 FR 44192 (July 22, 2020) (final rule approving relevant portions of SJV $PM_{2.5}$ Plan for 2006 $PM_{2.5}$ NAAQS purposes).

[9] 2018 $PM_{2.5}$ Plan, Chapter 4, Section 4.4 (''CARB Emission Reduction Commitment for the San Joaquin Valley'') and Valley State SIP Strategy, Chapter 3 (''Supplemental State Commitment from the Proposed State Measures for the Valley'').

previously approved into the SIP.[10] We are deferring action on the remaining portions of the Valley Incentive Measure.

As noted in section I above, the EPA previously proposed to fully approve the Valley Incentive Measure and to credit the measure with 5.9 tpd of NO_X reductions and 0.3 tpd of direct $PM_{2.5}$ reductions toward the 2024 aggregate tonnage commitments in the 2006 NAAQS Plan but did not finalize this proposal because, as of the date of our final action on the 2006 NAAQS Plan, we had not yet approved the Valley Incentive Measure into the SIP.[11] In this rule we are finalizing our proposal only with respect to those portions of the Valley Incentive Measure, as amended, that pertain to incentive projects implemented under California's Carl Moyer Memorial Air Quality Standards Attainment Program (Carl Moyer Program) and Funding Agricultural Replacement Measures for Emission Reductions Program (FARMER Program). We are deferring action on those portions of the Valley Incentive Measure that pertain to incentive projects implemented under the United States Department of Agriculture's Natural Resources Conservation Service (NRCS) Environmental Quality Incentives Program (EQIP). The docket for this rulemaking contains a copy of those portions of the Valley Incentive Measure, as amended and clarified by the Technical Corrections Document and the 2021 Clarification Document, that we are approving into the SIP.[12] For convenience, we refer to those portions of the Valley Incentive Measure as the ''Amended Valley Incentive Measure.''

As we explained in the TSD supporting our proposed rule, the Carl Moyer projects that CARB may implement to fulfill its commitments in the Valley Incentive Measure are those projects subject to either ''The Carl Moyer Program Guidelines, Approved Revisions 2011,'' revised December 18, 2015 (the ''2011 Carl Moyer Guidelines''), or ''The Carl Moyer Program Guidelines, 2017 Revisions,'' approved April 27, 2017 (the ''2017 Carl Moyer Guidelines'').[13] The FARMER projects that CARB may implement to fulfill its commitments in the Valley Incentive Measure are those projects subject to the ''Final: Funding Agricultural Replacement Measures for Emission Reductions (FARMER) Program Guidelines,'' release date: February 16, 2018 (''2018 FARMER Guidelines''), which generally must comply with the 2017 Carl Moyer Guidelines.[14]

CARB's SIP submission and related support documents indicate that the portions of the Valley Incentive Measure, as amended, that pertain to incentive projects implemented under the Carl Moyer Program and FARMER Program will achieve 4.83 tpd of NO_X reductions and 0.24 tpd of $PM_{2.5}$ reductions by 2024.[15] We are, therefore, approving CARB's commitments to achieve 4.83 tpd of NO_X reductions and 0.24 tpd of $PM_{2.5}$ reductions by the beginning of 2024 through implementation of the Amended Valley Incentive Measure, and crediting the measure with these amounts of NO_X and $PM_{2.5}$ emission reductions toward CARB's aggregate tonnage commitments for 2024 in the 2006 NAAQS Plan.[16] The 2006 NAAQS Plan shows that the San Joaquin Valley needs to achieve an additional 33.9 tpd of NO_X reductions and 2.2 tpd of $PM_{2.5}$ reductions beyond baseline measures to attain the 2006 $PM_{2.5}$ NAAQS by December 31, 2024.[17] Thus, the SIP-creditable emission reductions attributed to the Amended Valley Incentive Measure constitute 14.2 percent of the additional NO_X reductions (4.83/33.9 tpd) and 10.9 percent of the additional $PM_{2.5}$ reductions (0.24/2.2 tpd) necessary for attainment of the 2006 $PM_{2.5}$ NAAQS in the San Joaquin Valley by December 31, 2024.[18]

Under longstanding guidance, the EPA has recommended presumptive limits on the amounts of emission reductions from certain voluntary and other nontraditional measures that may be credited in a SIP. Specifically, for voluntary mobile source emission reduction programs, the EPA has identified a presumptive limit of three percent of the total projected future year emission reductions required to attain the appropriate NAAQS, and for any particular SIP submittal to demonstrate attainment or maintenance of the NAAQS or progress toward attainment (RFP), three percent of the specific statutory requirement.[19] The EPA may, however, approve measures for SIP credit in amounts exceeding the presumptive limits under certain

[10] 85 FR 44192, 44205–44206 (July 22, 2020) (codifying CARB's aggregate tonnage commitments at 40 CFR 52.220(c)(536)((ii)(A)(*2*).

[11] Id. at 44204.

[12] The portions of the Valley Incentive Measure that we are approving into the SIP are identified in two documents: (1) ''CARB Resolution 19–26, approved portions'' and (2) ''Technical Corrections Document, approved portions.'' These two documents are attached to the email dated June 2, 2021, from Rebecca Newhouse (EPA) to Sylvia Vanderspek (CARB), RE: ''SJV ag tractor incentive measure,'' and are available in the docket for this rulemaking.

[13] TSD, 10–11.

[14] TSD, 16–17 (noting that all FARMER projects that CARB relies on to comply with the Valley Incentive Measure are subject to the 2017 Carl Moyer Guidelines, future approved guidelines, and current and future program advisories and mail-outs, except as modified by CARB). See also Demonstration, 43–45 and 2018 FARMER Guidelines, 17–18. All FARMER projects identified in the project list included in CARB's SIP submission are subject to the 2017 Carl Moyer Guidelines. Demonstration, Appendix J (''San Joaquin Valley Agricultural Equipment Incentive Measure, FARMER Project List''). Therefore, references herein to the 2017 Carl Moyer Guidelines apply to both Carl Moyer projects and FARMER projects. Should CARB revise the 2018 FARMER Guidelines at any point before May 15, 2025, it will be obligated under paragraph D.2 of CARB Resolution 19–26 to provide, in the annual demonstration report for the relevant year, a ''description of any changes to the 2018 FARMER Guidelines and their related impacts on program integrity.'' TSD, 17 (referencing Valley Incentive Measure, 11 (CARB Resolution 19–26, para. D.2)).

[15] CARB, ''Appendix I, San Joaquin Valley Agricultural Equipment Incentive Measure, NRCS Project List,'' available as ''Appendix I—Detailed'' at *https://ww2.arb.ca.gov/resources/documents/implementation-state-sip-strategy* (last visited November 16, 2021) and also available as ''ag_appx_i_detailed_021120.xlsx'' in the docket for this rulemaking. The ''NRCS Summary'' tab of Appendix I identifies 1.07 tpd of NO_X emission reductions and 0.06 tpd of $PM_{2.5}$ emission reductions achieved in 2024 through EQIP projects implemented by the NRCS. Subtraction of these amounts from CARB's 2024 tonnage commitments in the Valley Incentive Measure (5.9 tpd NO_X reductions and 0.3 tpd $PM_{2.5}$ reductions) results in 4.83 tpd of NO_X reductions (5.9—1.07 tpd) and 0.24 tpd of $PM_{2.5}$ reductions (0.3—0.06 tpd), which CARB anticipates achieving through implementation of Carl Moyer and FARMER projects.

[16] 85 FR 44192, 44205–44206 (July 22, 2020) (codifying CARB's aggregate tonnage commitments at 40 CFR 52.220(c)(536)((ii)(A)(*2*). In this rule we are codifying, in the appropriate paragraph under 40 CFR 52.220(c), CARB's commitments to achieve 4.83 tpd of NO_X reductions and 0.24 tpd of $PM_{2.5}$ reductions by the beginning of 2024 through implementation of the Amended Valley Incentive Measure thereby enabling the EPA and citizens to enforce these commitments under the CAA. Our codification of these commitments constitutes a finding that CARB has achieved 4.83 tpd of the NO_X reductions and 0.24 tpd of the $PM_{2.5}$ reductions that CARB must achieve by 2024 under its aggregate tonnage commitment at 40 CFR 52.220(c)(536)((ii)(A)(*2*).

[17] 85 FR 44192, 44204 (Table 1) (July 22, 2020).

[18] These calculations are consistent with the EPA's recommended method for calculating the percentage of emission reductions attributed to voluntary mobile source measures for purposes of comparison to the EPA's presumptive limits on SIP credit for such measures. See EPA, ''Guidance on Incorporating Voluntary Mobile Source Emission Reduction Programs in State Implementation Plans (SIPs),'' October 24, 1997 (''1997 VMEP''), 5, fn. 3. In our March 27, 2020 proposal (85 FR 17382, 17412), we erroneously calculated the percentage of emission reductions attributed to the Valley Incentive Measure as a percentage of the total emission reductions needed for attainment from the base year to the attainment year, rather than as a percentage of the incremental reductions needed beyond baseline measures in the attainment year.

[19] EPA, ''Guidance on Incorporating Voluntary Mobile Source Emission Reduction Programs in State Implementation Plans (SIPs),'' October 24, 1997, 5.

circumstances, and where a clear and convincing justification is made by the State as to why a higher limit should apply in its case.[20]

The San Joaquin Valley's topography and meteorology present significant challenges for air quality. As stated in the 2018 $PM_{2.5}$ Plan, ''the surrounding mountains trap pollution and block airflow'' and ''[t]emperature inversions, while present to some degree throughout the year, can last for days during the winter, holding in nighttime accumulations of pollutants.'' [21] In addition, the population of the area continues to grow at a rate higher than the statewide growth rate, leading to increased vehicular traffic along major highways that run through the San Joaquin Valley.[22] Given these unique challenges, both the State and District continue to implement both traditional and non-traditional emission reduction strategies to attain the $PM_{2.5}$ standards in the San Joaquin Valley, including regulatory programs, incentive programs, and rigorous outreach and education efforts.[23] Over the past several decades, the State and District have developed and implemented several comprehensive plans to address attainment of the NAAQS for ozone and particulate matter.[24] These attainment plans have resulted in the State's and District's adoption of numerous regulations for stationary, area, and mobile sources, including some of the most stringent control measures in the nation.[25] Given the air quality needs of the area, the numerous control measures that both the State and District have adopted and implemented in the San Joaquin Valley to date, the State's and District's successful implementation of the Carl Moyer program over the last two decades, and our experience to date quantifying emission reductions achieved through this program,[26] we believe it is appropriate to allow the State to rely on the Amended Valley Incentive Measure to achieve 14.2 percent (4.83 tpd) of the additional NO_X reductions and 10.9 percent (0.24 tpd) of the additional direct $PM_{2.5}$ reductions necessary for the area to attain the 2006 $PM_{2.5}$ NAAQS by the end of 2024. Moreover, all Carl Moyer and FARMER projects are subject to detailed contract provisions that CARB may enforce against the grantee at any time during the contract term, a program feature that further supports the State's reliance on the Amended Valley Incentive Measure for emission reductions exceeding the EPA's presumptive limits.[27] See Response 2.

CARB's SIP submission and related support documents also indicate that the Amended Valley Incentive Measure will achieve 4.46 tpd of NO_X reductions and 0.26 tpd of $PM_{2.5}$ reductions by 2025.[28] We are, therefore, approving CARB's commitments to achieve 4.46 tpd of NO_X reductions and 0.26 tpd of $PM_{2.5}$ reductions by the beginning of 2025, thereby making these portions of the Amended Valley Incentive Measure enforceable under the CAA and creditable toward the attainment control strategy in the 2012 NAAQS Plan.[29] In a separate rulemaking on the 2012 NAAQS Plan, the EPA will identify the specific amounts of NO_X and $PM_{2.5}$ emission reductions that may be attributed to the Amended Valley Incentive Measure as part of the State's control strategy for attaining the 2012 $PM_{2.5}$ NAAQS. If those amounts of NO_X and $PM_{2.5}$ emission reductions exceed the EPA's presumptive limits on the use of emission reductions from voluntary measures for SIP purposes, the EPA will, as part of that rulemaking, evaluate the SIP submission for the Amended Valley Incentive Measure to determine whether such use is justified.

III. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received comments from Earthjustice objecting to our proposal.[30] We also received comments from 27 entities that express only support for our proposal and do not require a response.[31] We summarize and respond to all comments from Earthjustice that pertain to the Amended Valley Incentive Measure—*i.e.,* those portions of the measure, as amended and

[20] EPA, ''Improving Air Quality with Economic Incentive Programs'' January 2001 (''2001 EIP Guidance''), 158 (recommending use of 2001 EIP Guidance to implement programs achieving more than the 3 percent limit where the State can directly implement and enforce the program against identifiable sources); EPA, ''Diesel Retrofit and Replacement Projects: Quantifying and Using Their Emission Benefits in SIPs and Conformity: Guidance for State and Local Air and Transportation Agencies,'' March 2018 (''2018 Diesel Retrofits Guidance''), 12, 28 (noting that EPA will allow the 3 percent cap to be exceeded if the cap hinders the implementation of effective voluntary control measures, subject to notice and comment rulemaking); and EPA, ''Guidance on Incorporating Bundled Measures in a State Implementation Plan,'' August 16, 2005, 8, n. 6 (noting that EPA may approve measures into a SIP exceeding the presumptive 6 percent limit for stationary source measures ''where a clear and convincing justification is made by the State as to why a higher limit should apply in its case''). See also EPA, ''Incorporating Emerging and Voluntary Measures in a State Implementation Plan (SIP),'' September 2004, 9 (''2004 Emerging and Voluntary Measures Guidance'').

[21] 2018 $PM_{2.5}$ Plan, Chapter 2, 2–1.

[22] Id. at 2–4.

[23] Id. at 2–2.

[24] See, *e.g.,* 69 FR 30005 (May 26, 2004) (approving plan to attain the 1987 PM_{10} NAAQS), 76 FR 69896 (November 9, 2011) (partially approving and partially disapproving plan to attain the 1997 $PM_{2.5}$ NAAQS), 77 FR 12652 (March 1, 2012) (approving plan to attain the 1997 8-hour ozone NAAQS), 81 FR 19492 (April 5, 2016) (approving plan to attain the 1979 1-hour ozone NAAQS), and 85 FR 44192 (July 22, 2020) (approving plan to attain the 2006 $PM_{2.5}$ NAAQS).

[25] 85 FR 44192 (July 22, 2020) (finding, inter alia, that California's attainment plan for the 2006 $PM_{2.5}$ NAAQS in the SJV includes the best available control measures and most stringent measures as required by CAA section 188(e)). See also 85 FR 17382, 17412–17413 (March 27, 2020) (providing rationale for State's reliance on incentive measures for emission reductions exceeding 3 percent presumptive limit).

[26] The EPA has approved two incentive-based SIP submissions from CARB that rely on Carl Moyer projects for SIP emission reduction credit. See 86 FR 3820 (January 15, 2021) (full approval of South Coast incentive measure) and 81 FR 53300 (August 12, 2016) (limited approval/disapproval of ''Emission Reduction Report'' for San Joaquin Valley).

[27] 2011 Carl Moyer Guidelines, Part I, Chapter 3, Section Y (''Minimum Contract Requirements'') and 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 3, Section V (''Minimum Contract Requirements''), para. 11 (''Repercussions for Nonperformance'').

[28] CARB, ''Appendix I, San Joaquin Valley Agricultural Equipment Incentive Measure, NRCS Project List,'' available as ''Appendix I—Detailed'' at *https://ww2.arb.ca.gov/resources/documents/implementation-state-sip-strategy* (last visited November 16, 2021) and also available as ''ag_appx_i_detailed_021120.xlsx'' in the docket for this rulemaking. The ''NRCS Summary'' tab of Appendix I identifies 0.64 tpd of NO_X emission reductions and 0.04 tpd of $PM_{2.5}$ emission reductions achieved in 2025 through EQIP projects implemented by the U.S. Department of Agriculture's Natural Resources Conservation Service. Subtraction of these amounts from CARB's 2025 tonnage commitments in the Valley Incentive Measure (5.1 tpd NO_X reductions and 0.3 tpd $PM_{2.5}$ reductions) results in 4.46 tpd of NO_X reductions (5.1–0.64 tpd) and 0.26 tpd of $PM_{2.5}$ reductions (0.3–0.04 tpd), which CARB anticipates achieving through implementation of Carl Moyer and FARMER projects. Note that the EPA's estimate of the $PM_{2.5}$ emission reductions achieved through Carl Moyer and FARMER projects in 2025 (0.26 tpd) is slightly higher than its estimate of the $PM_{2.5}$ emission reductions achieved through Carl Moyer and FARMER projects in 2024 (0.24 tpd, see n. 15 *supra*) due to small differences in the projected emission reductions for 2024 and 2025 that CARB identified in Appendix I—Detailed and ''Carl Moyer/FARMER Emissions Reductions Calculator,'' available as ''Appendices H and J—Detailed'' at *https://ww2.arb.ca.gov/resources/documents/implementation-state-sip-strategy.* See TSD, 28, n. 111.

[29] We are codifying, in the appropriate paragraph under 40 CFR 52.220(c), CARB's commitments to achieve 4.46 tpd of NO_X reductions and 0.26 tpd of $PM_{2.5}$ reductions by the beginning of 2025 through implementation of the relevant portions of the Valley Incentive Measure, as amended.

[30] Letter dated April 23, 2020, from Paul Cort, Earthjustice, to Rynda Kay, EPA, Region IX, Subject: ''Docket ID No. EPA–R09–OAR–2020–0079.''

[31] The entities that expressed support for our proposal include 17 agriculture-related trade organizations and 10 individual farmers. All of these letters are available in the docket for this rulemaking.

clarified, that pertain to implementation of Carl Moyer and FARMER projects.[32]

Because we are deferring action on those portions of the Valley Incentive Measure that pertain to EQIP projects, we are not responding to comments pertaining to these portions of the measure at this time. We will respond to these comments in a subsequent rulemaking or, if we substantially revise our proposal with respect to the portions of the Valley Incentive Measure that pertain to EQIP projects, we will provide another opportunity for public comment on that revised proposal.

Comment 1: Earthjustice states that CARB and the SJVUAPCD have used promises of voluntary emission reductions supported by incentive funds to cure all number of planning and regulatory failures, and that without a detailed accounting, there is no reasonable basis for concluding that the reductions achieved in this program are surplus to reductions that have been credited or assumed elsewhere. Citing the definition of ''surplus'' provided in the EPA's technical support document (TSD), Earthjustice claims that the EPA has not explained how these particular emission reductions are surplus to the various other voluntary emission reductions relied upon in the SIP. For example, Earthjustice cites the emission reductions relied upon to satisfy the CAA section 185 requirements for this area (SJVUAPCD Rule 3170); the District's assumption that mitigation funds will offset the growth in oil and gas emissions as a result to the Kern County Program environmental impact report (EIR); the District's claim that its boiler, winery, and other rules meet minimum control requirements by requiring mitigation funds to achieve reductions in lieu of installing advanced controls (*e.g.,* SJVUAPCD Rule 4320 and Rule 4694); and the District's retirement of surplus emission reductions to demonstrate the equivalency of its new source review program (SJVUAPCD Rule 2201). According to Earthjustice, these voluntary incentive programs have become ''an accounting shell game'' and the EPA cannot deem the associated emission reductions surplus until all of the ''overlapping'' incentive program reductions are analyzed.

Response 1: We disagree with these claims. As a general matter, an incentive-based measure may be credited toward the control strategy in an attainment plan if the State demonstrates that the emission reductions achieved by the measure will not be ''double-counted'' in the same attainment plan. The EPA's March 2018 guidance document entitled ''Diesel Retrofit and Replacement Projects: Quantifying and Using Their Emission Benefits in SIPs and Conformity: Guidance for State and Local Air and Transportation Agencies,'' March 2018 (''2018 Diesel Retrofits Guidance'') states that ''[e]mission reductions are considered 'surplus' if they are not otherwise relied on to meet other applicable air quality attainment or maintenance requirements for that particular NAAQS pollutant (*i.e.,* there can be no double-counting of emission reductions).'' [33] Similarly, the EPA's October 1997 guidance document entitled ''Guidance on Incorporating Voluntary Mobile Source Emission Reduction Programs in State Implementation Plans (SIPs),'' October 24, 1997 (''1997 VMEP''), states that ''VMEP emission reductions may not be substituted for mandatory, required emission reductions,'' and that ''States may submit to EPA for approval any program that will result in emission reductions in addition to those already credited in a relevant attainment or maintenance plan, or used for purposes of SIP demonstrations such as conformity, rate of progress, or emission credit trading programs.[34]

The EPA's intent in these guidance documents was to ensure that emission reductions achieved through implementation of voluntary programs, including incentive-based vehicle replacement programs, are not double-counted in the attainment or maintenance plan for a particular NAAQS.[35] Although two other EPA guidance documents cited in the EPA's TSD state that emission reductions achieved by voluntary programs should also be surplus to other adopted state air quality programs (even those not in the relevant SIP),[36] these guidance documents provide only interpretive guidance and are not binding on the EPA. In the context of a control strategy to provide for attainment of a particular NAAQS, we find that an incentive-based measure need not achieve emission reductions that are surplus to all adopted state air quality programs and may, instead, be credited toward the control strategy if the State demonstrates that the measure achieves emission reductions that are not already accounted for in the particular attainment plan at issue.

Thus, to satisfy the surplus (*i.e.,* additionality) criterion in the EPA's longstanding guidance, the Amended Valley Incentive Measure need only be surplus to the control measures and programs that are accounted for in the attainment plan(s) in which CARB relies upon this measure. On May 10, 2019, California submitted an integrated $PM_{2.5}$ attainment plan for the San Joaquin Valley that includes, among other things, a Serious area plan to provide for attainment of the 2006 24-hour $PM_{2.5}$ NAAQS by 2024 (''2006 NAAQS Plan'') and a Serious area plan to provide for attainment of the 2012 annual $PM_{2.5}$ NAAQS by 2025 (the ''2012 NAAQS Plan'') (collectively the ''SJV $PM_{2.5}$ Plan'').[37] The 2006 NAAQS Plan relies on the 2024 tonnage commitment in the Amended Valley Incentive Measure to achieve a portion of the emission reductions necessary for attainment of these NAAQS by the end of 2024,[38] and the 2012 NAAQS Plan relies on the 2025 tonnage commitment in the Amended Valley Incentive Measure to achieve a portion of the emission reductions necessary for attainment of this NAAQS by the end of 2025.[39] Accordingly, we have reviewed both the baseline emissions projections for off-road mobile, diesel agricultural equipment and the attainment control strategy in the SJV $PM_{2.5}$ Plan to

[32] CARB Resolution 19–26 (December 12, 2019), Technical Corrections Document, and 2021 Clarification Document. All references to the Amended Valley Incentive Measure herein are to the portions of CARB Resolution 19–26 and the Technical Corrections Document that the EPA is approving (*i.e.,* excluding those portions that pertain to EQIP projects implemented by the NRCS), as indicated in the documents in the rulemaking docket entitled ''CARB Resolution 19–26, approved portions'' and ''Technical Corrections Document, approved portions.''

[33] 2018 Diesel Retrofits Guidance, 27.

[34] 1997 VMEP, 6.

[35] That is, if the emission reductions achieved by the voluntary program have already been credited in the attainment or maintenance plan for the particular NAAQS at issue, then those emission reductions cannot be treated as ''surplus'' and, therefore, cannot be credited in the same attainment plan.

[36] 2001 EIP Guidance, section 4.1 and 2004 Emerging and Voluntary Measures Guidance, 3.

[37] Letter dated May 9, 2019, from Richard Corey, Executive Officer, CARB, to Mike Stoker, Regional Administrator, EPA Region 9 (transmitting 2018 $PM_{2.5}$ Plan and Valley State SIP Strategy). The SJVUAPCD developed and adopted the 2018 $PM_{2.5}$ Plan, and CARB developed and adopted the Valley State SIP Strategy. 85 FR 44192, 44193.

[38] 2018 $PM_{2.5}$ Plan, Chapter 4, Section 4.4 (''CARB Emission Reduction Commitment for the San Joaquin Valley'') and Valley State SIP Strategy, Chapter 3 (''Supplemental State Commitment from the Proposed State Measures for the Valley''). See also 85 FR 17415–17416 (March 27, 2020) (proposed rule to approve relevant portions of SJV $PM_{2.5}$ Plan for 2006 $PM_{2.5}$ NAAQS purposes, discussing plan's reliance on San Joaquin Valley Agricultural Incentive Measure) and 85 FR 44192 (July 22, 2020) (final rule approving relevant portions of SJV $PM_{2.5}$ Plan for 2006 $PM_{2.5}$ NAAQS purposes).

[39] 2018 $PM_{2.5}$ Plan, Chapter 4, Section 4.4 (''CARB Emission Reduction Commitment for the San Joaquin Valley'') and Valley State SIP Strategy, Chapter 3 (''Supplemental State Commitment from the Proposed State Measures for the Valley'').

determine whether the emission reductions to be achieved through implementation of the Amended Valley Incentive Measure have already been credited in this attainment plan.

With respect to mobile source emissions projections, air quality plans, including the SJV $PM_{2.5}$ Plan, rely on emissions estimates that have been derived from the use of emissions models or other emissions projection methodologies that assume certain rates of replacement of older equipment with newer equipment manufactured to meet more stringent emissions standards (*i.e.,* fleet turnover). Use of such models and methodologies is the standard emission estimation technique, and the emissions projections made using them are generally considered sufficiently accurate for plan development purposes. The assumptions regarding fleet turnover are similar to other planning assumptions used to develop air quality plans, such as assumptions regarding population and employment growth and changes in vehicle activity. Such assumptions are not enforceable in the way that emissions limitations are enforceable. Rather, the obligation on the state for plan development is to use the latest planning assumptions and most recently developed emissions models and inventories.[40]

In the case of the SJV $PM_{2.5}$ Plan, the emissions projections reflect the latest planning assumptions and emissions inventories available at the time of plan development. The Demonstration states that the projected baseline inventory for off-road mobile, diesel agricultural equipment in the 2018 $PM_{2.5}$ Plan is based on a 2011 emissions inventory described in a CARB report entitled, ''Emission Inventory for Agricultural Diesel Vehicles,'' August 2018 (''Agricultural EI Report'').[41] This 2011 emission inventory is based on a 2008 survey of agricultural producers, custom operators, and first processors for self-propelled diesel agricultural equipment over 25 horsepower in size, as well as data on farms and acreage from a 2007 census conducted by the U.S. Department of Agriculture (USDA).[42] According to CARB, the 2011 emissions inventory for agricultural equipment in the 2018 $PM_{2.5}$ Plan was derived only from base year inputs that do not account for incentive programs and does not reflect the future-year population forecast that accounts for incentive programs.[43] In response to the EPA's request for clarification, CARB provided this further explanation by email dated November 13, 2020:

> The baseline emissions in the SJV $PM_{2.5}$ Plan inventory were developed from the 2008 survey and 2007 USDA data on acres harvested, and include no incentives projects. All years after 2008 are projected populations and emissions reflect natural not incentivized turnover. The downward slope and reduction in emissions over time in the baseline is solely due to natural turnover, the replacement of older engines due to mechanical deterioration and the business-as-usual replacement practices.[44]

To illustrate, CARB provided a figure showing baseline projected NO_X emissions from 2015–2049 for three different scenarios: a projection reflecting only natural turnover, a projection including existing incentive projects, and a projection including both existing and anticipated future incentive projects.[45] The downward slopes of the two curves that include incentive projects are initially steeper than the projection reflecting only natural turnover, indicating that incentive projects result in accelerated turn-over of vehicles compared to business as usual. We find the documentation in the SJV $PM_{2.5}$ Plan and additional information provided by CARB sufficient to confirm that the baseline emissions projections for off-road diesel agricultural equipment sources in the SJV $PM_{2.5}$ Plan do not account for emission reductions to be achieved through implementation of the Amended Valley Incentive Measure.

The attainment control strategy in the SJV $PM_{2.5}$ Plan also does not specifically rely on implementation of Carl Moyer or FARMER projects for SIP emission reduction credit. As explained in the EPA's proposed rule to approve relevant portions of the SJV $PM_{2.5}$ Plan for 2006 $PM_{2.5}$ NAAQS purposes, the majority of the NO_X emission reductions needed for attainment of the 2006 $PM_{2.5}$ NAAQS in the SJV by 2024 come from baseline measures, none of which rely on implementation of Carl Moyer or FARMER projects.[46] For the remainder of the NO_X reductions necessary for attainment of the 2006 $PM_{2.5}$ NAAQS by 2024, the SJV $PM_{2.5}$ Plan relies primarily on CARB's and the District's enforceable commitments to achieve additional emission reductions, in the aggregate, through implementation of new or revised measures by the beginning of 2024.[47] The SJV $PM_{2.5}$ Plan also relies on these same enforceable commitments by CARB and the District to achieve the additional emission reductions needed for attainment of the 2012 $PM_{2.5}$ NAAQS by 2025.[48] The SJV $PM_{2.5}$ Plan indicates that CARB anticipates fulfilling a portion of these emission reduction commitments through implementation of incentive funds for off-road diesel agricultural equipment,[49] but the plan does not specifically credit any incentive program with emission reductions, as the EPA has not previously approved any incentive-

[40] EPA, ''Emissions Inventory Guidance for Implementation of Ozone and Particulate Matter National Ambient Air Quality Standards (NAAQS) and Regional Haze Regulations,'' EPA–454/B–17–002, May 2017, 28 (noting that California's prior emissions model for estimating nonroad source emissions for SIP purposes, called OFFROAD2007, has been replaced with category-specific methods for many categories). CARB uses a category-specific methodology for estimating emissions from off-road mobile, diesel agricultural equipment. See CARB's mobile source emissions inventory website at *https://ww2.arb.ca.gov/our-work/programs/mobile-source-emissions-inventory/road-documentation/msei-documentation-road.*

[41] Demonstration, 59–60 and Appendix G. CARB and the EPA refer to the portion of the SJV $PM_{2.5}$ Plan that the SJVUAPCD developed and adopted as the ''2018 $PM_{2.5}$ Plan.''

[42] Id.

[43] Demonstration, 60 (referencing sections 3–5 of Agricultural EI Report for base year inputs, and sections 2 and 6–8 of Agricultural EI Report for population forecasts that include incentive programs).

[44] Email dated November 13, 2020, from Austin Hicks, CARB, to Rebecca Newhouse, EPA Region IX, Subject: ''RE: 9/10 meeting: suggested agenda and request for Carl Moyer drayage project documentation.'' See also email dated September 9, 2020 from Austin Hicks, CARB, to Rebecca Newhouse, EPA Region IX, Subject: ''RE: Follow-up on SJV $PM_{2.5}$ Plan ag equipment inventory question'' (noting that, ''[i]n the forecast, equipment populations are subject to a survival curve, developed by equipment type, equipment horsepower, and the size of the farm where it is used. Retirement trends vary from very aggressive on the largest farms (useful life of 10 years), to very slow on the smallest farms (useful life up to 40 to 50 years). Retired vehicles are modeled as being replaced by new and used equipment, again depending on equipment type, size and farm size parameters. The largest farms purchase almost exclusively new equipment, while the smallest farms purchase 10–30 year old equipment in most cases.'')

[45] Email dated November 13, 2020 from Austin Hicks, CARB, to Rebecca Newhouse, EPA Region IX, Subject: ''RE: 9/10 meeting: suggested agenda and request for Carl Moyer drayage project documentation.''

[46] 85 FR 17382, 17410–17415 (March 27, 2020) and EPA Region IX, Technical Support Document, ''EPA General Evaluation, San Joaquin Valley $PM_{2.5}$ Plan for the 2006 $PM_{2.5}$ NAAQS,'' February 2020, section V (identifying SIP-approved District rules credited in the SJV $PM_{2.5}$ Plan's future baseline emissions estimates and attainment control strategy).

[47] 85 FR 17382, 17410–17415 and 85 FR 44192, 44198 and 44204 (July 22, 2020) (Response 3.A and Table 1). CARB's and the SJVUAPCD's aggregate tonnage commitments are codified in 40 CFR 52.220(c)(536)(ii)(A)(*2*) and 52.220(c)(537)(ii)(B)(*3*).

[48] 2018 $PM_{2.5}$ Plan, Chapter 4, Section 4.4 (''CARB Emission Reduction Commitment for the San Joaquin Valley'') and Valley State SIP Strategy, Chapter 3 (''Supplemental State Commitment from the Proposed State Measures for the Valley'').

[49] 2018 $PM_{2.5}$ Plan, Chapter 4, Table 4–8 and Table 4–9 (identifying CARB measures scheduled for action and implementation in the San Joaquin Valley) and 85 FR 17382, 17414 (Table 7, ''Status of CARB Compliance with Control Measure Commitments for the San Joaquin Valley—Continued'').

based control measure for SIP credit in this plan.[50] Thus, the Amended Valley Incentive Measure is the first incentive-based control measure to be approved into the SJV $PM_{2.5}$ Plan and will achieve emission reductions beyond those already credited in this plan.

Although the EPA did not previously credit the Amended Valley Incentive Measure toward the control strategy in the SJV $PM_{2.5}$ Plan, our approval of this measure represents progress in CARB's implementation of the SIP-approved control strategy in this plan. In addition to specific emission reduction commitments for 2024 and 2025, the SJV $PM_{2.5}$ Plan contains commitments by CARB to bring certain defined measures, including a proposed incentive-based measure for agricultural equipment, to the Board for consideration according to the schedule set forth in the plan.[51] CARB's adoption, implementation, and submission of the Valley Incentive Measure achieves a portion of CARB's aggregate NO_X and $PM_{2.5}$ emission reduction commitments in the SIP (specifically, 4.83 and 4.46 tpd of CARB's NO_X reduction commitments and 0.24 and 0.26 tpd of CARB's $PM_{2.5}$ reduction commitments for 2024 and 2025, respectively),[52] and satisfies the State's commitment to bring a proposed incentive-based measure for agricultural equipment to the Board for consideration.

Earthjustice contends that the EPA must explain how the emission reductions achieved through implementation of the Valley Incentive Measure are ''surplus to the various other voluntary emission reductions relied upon in the SIP.'' As stated above, however, to satisfy the surplus criterion in the EPA's longstanding guidance, the Amended Valley Incentive Measure need only be surplus to the control measures and programs that are credited toward the attainment control strategies in the 2006 NAAQS Plan and 2012 NAAQS Plan. The SJV $PM_{2.5}$ Plan identifies 33 District measures achieving direct $PM_{2.5}$ and/or NO_X emissions reductions that support attainment of the $PM_{2.5}$ NAAQS in the San Joaquin Valley.[53] With the exception of SJVUAPCD Rule 4320, none of the programs or regulations cited by Earthjustice (*i.e.,* SJVUAPCD Rule 3170, mitigation funds related to the Kern County Program EIR, SJVUAPCD Rule 4694, or SJVUAPCD Rule 2201) is included among these 33 baseline measures.[54] Because these programs and regulations are not part of the attainment control strategy in either the 2006 NAAQS Plan or the 2012 NAAQS Plan, they are not relevant to our evaluation of the Amended Valley Incentive Measure.[55]

SJVUAPCD Rule 4320 is identified as a baseline control measure in the SJV $PM_{2.5}$ Plan.[56] The EPA approved Rule 4320, adopted October 16, 2008, into the California SIP on March 25, 2011, but noted that the rule did not qualify for SIP credit for attainment planning purposes until the District submitted adequate supporting documentation.[57] Although the SJV $PM_{2.5}$ Plan relies on NO_X and $PM_{2.5}$ emission reductions from Rule 4320, which is not eligible for SIP credit at this time, the District's inclusion of this rule in the attainment control strategy for the 2006 NAAQS Plan has no material effect on our evaluation of that attainment demonstration or the Amended Valley Incentive Measure because the emission reductions attributed to Rule 4320 are de minimis. According to the District's control strategy analysis in Appendix C of the 2018 $PM_{2.5}$ Plan, the District has attributed 0.60 and 0.21 tpd of NO_X and $PM_{2.5}$ emission reductions, respectively, to Rule 4320 in 2024,[58] amounting to 0.3 percent of the total NO_X reductions and 3.3 percent of the total $PM_{2.5}$ reductions necessary for attainment of the 2006 $PM_{2.5}$ NAAQS by 2024.[59] Similarly, the District has attributed 0.64 and 0.23 tpd of NO_X and $PM_{2.5}$ emission reductions, respectively, to Rule 4320 in 2025,[60] amounting to 0.3 percent of the total NO_X reductions and 3.6 percent of the total $PM_{2.5}$ reductions necessary for attainment of the 2012 $PM_{2.5}$ NAAQS by 2025.[61] These amounts of emission reductions have a de minimis impact on our evaluation of the relevant attainment demonstrations and of the Amended Valley Incentive Measure. Moreover, the commenter has provided no support for a conclusion that Rule 4320 relies on implementation of Carl Moyer or FARMER projects, nor any support for a conclusion that the NO_X or $PM_{2.5}$ emission reductions attributed to this rule in the SJV $PM_{2.5}$ Plan include emission reductions from such incentive projects.[62] We have no information before us indicating that

[50] 85 FR 44192, 44198–44199.

[51] 40 CFR 52.220(c)(536)(ii)(A)(*2*) (referencing CARB Resolution 18–49 (October 25, 2018) and attachments) and Valley State SIP Strategy, 35–38 (identifying CARB measures scheduled for action and implementation in the San Joaquin Valley); see also 85 FR 17382, 17413–17414 (Table 7, ''Status of CARB Compliance with Control Measure Commitments for the San Joaquin Valley).

[52] See footnotes 16 and 28, supra.

[53] 2018 $PM_{2.5}$ Plan, Ch. 4, Table 4–1, Table 4–2, Table 4–3, and App. C.

[54] Id. See also EPA, ''Technical Support Document, General Evaluation, San Joaquin Valley Plan for the 2006 $PM_{2.5}$ NAAQS,'' February 2020 (''General Evaluation TSD''), section V (listing baseline measures contributing to attainment of 2006 $PM_{2.5}$ NAAQS but not including SJVUAPCD Rule 3170, mitigation funds related to Kern County Program EIR, SJVUAPCD Rule 4694, or SJVUAPCD Rule 2201). We note also that the stated purpose of SJVUAPCD Rule 3170 is to address CAA requirements for the ozone NAAQS, not the $PM_{2.5}$ NAAQS. *See* Rule 3170, section 1.0 (''The purpose of this rule is to satisfy requirements specified in Section 185 and Section 182(f) of the 1990 amendments to the federal Clean Air Act . . .'').

[55] Even if these programs and regulations rely to some extent on Carl Moyer projects, our approval of the Valley Incentive Measure does not constitute ''double-counting'' of SIP emission reductions because these programs and regulations are not part of the attainment control strategy in the SJV $PM_{2.5}$ Plan.

[56] 2018 $PM_{2.5}$ Plan, Chapter 4, Table 4–1 and Table 4–2 (identifying baseline District regulations that reduce particulate matter and NO_X emissions in the San Joaquin Valley).

[57] 76 FR 16696 (March 25, 2011) and EPA, Region IX Air Division, ''Technical Support Document for EPA's Notice of Proposed Rulemaking for the California State Implementation Plan, San Joaquin Valley Unified Air Pollution Control District's Rule 4320, Advanced Emission Reduction Options for Boilers, Steam Generators and Process Heaters Greater than 5.0 MMbtu/hr,'' August 19, 2010.

[58] 2018 $PM_{2.5}$ Plan, Appendix C, C–69 (showing 0.60 tpd NO_X reductions and 0.21 tpd $PM_{2.5}$ reductions (winter average tpd) between 2013 base year and 2024 attainment year).

[59] The 2018 $PM_{2.5}$ Plan shows that 202.2 tpd of NO_X reductions and 6.4 tpd of $PM_{2.5}$ reductions from base year (2013) levels are necessary for the San Joaquin Valley to attain the 2006 $PM_{2.5}$ NAAQS by December 31, 2024. 2018 $PM_{2.5}$ Plan, revised App. H, Table H–6. Thus, rounding to the nearest tenth of a decimal, 0.6 tpd of NO_X reductions constitutes 0.3 percent of the necessary NO_X reductions (0.6/202.2), and 0.21 tpd of $PM_{2.5}$ reductions constitutes 3.3 percent of the necessary $PM_{2.5}$ reductions (0.21/6.4).

[60] 2018 $PM_{2.5}$ Plan, Appendix C, C–69 (showing 0.64 tpd NO_X reductions and 0.23 tpd $PM_{2.5}$ reductions (winter average tpd) between 2013 base year and 2024 attainment year).

[61] The 2018 $PM_{2.5}$ Plan shows that 207.4 tpd of NO_X reductions and 6.4 tpd of $PM_{2.5}$ reductions from base year (2013) levels are necessary for the San Joaquin Valley to attain the 2012 $PM_{2.5}$ NAAQS by December 31, 2025. 2018 $PM_{2.5}$ Plan, revised App. H, Table H–6. Thus, rounding to the nearest tenth of a decimal, 0.64 tpd of NO_X reductions constitutes 0.3 percent of the necessary NO_X reductions (0.64/202.2), and 0.23 tpd of $PM_{2.5}$ reductions constitutes 3.6 percent of the necessary $PM_{2.5}$ reductions (0.23/6.4).

[62] Rule 4320 requires that all emission units subject to the rule comply with one of three sets of requirements: (1) Emission limits and other control requirements for NO_X, carbon monoxide (CO), and particulate matter (PM) specified in sections 5.2 and 5.4 of the rule, (2) PM control requirements in section 5.4 of the rule and a requirement to pay an annual emissions fee to the District as specified in section 5.3 of the rule, or (3) applicable ''Low-use Unit'' requirements in section 5.5 of the rule. SJVUAPCD Rule 4320 (adopted October 16, 2008), section 5.1. To the extent the commenter intended to argue that section 5.3.2 of Rule 4320, the provision that allows sources to pay fees in lieu of installing advanced NO_X controls, relies on implementation of Carl Moyer or FARMER projects, this comment is unsubstantiated. See id. at section 5.3.2 (requiring continued payment of annual fees in accordance with section 5.3.1 ''until the unit either is permanently removed from use in the San Joaquin Valley Air Basin . . . or the operator demonstrates compliance with the applicable NO_X emission limits shown in Table 2'').

either Rule 4320 or the attainment demonstration in the SJV $PM_{2.5}$ Plan relies on any Carl Moyer or FARMER project that may also be used to satisfy the tonnage commitments in the Amended Valley Incentive Measure—*i.e.,* that there is any double-counting of emission reductions from the same incentive projects in this plan. Accordingly, we disagree with Earthjustice's suggestion that the Amended Valley Incentive Measure fails to meet the surplus (additionality) criterion because of the SJV $PM_{2.5}$ Plan's reliance on Rule 4320 as a baseline control measure.

Finally, under California State law, Carl Moyer funding is generally prohibited for any project that is required by any local, state, or federal statute, rule, regulation, memoranda of agreement or understanding, or other legally binding document in effect as of the date the grant is awarded.[63] CARB states in the Demonstration that all emission reductions associated with turning over older and dirtier agricultural equipment to cleaner equipment are ''surplus to District and State regulations because agricultural equipment is not subject to any District or State regulation.'' [64] CARB also identifies in the Demonstration those portions of the 2011 and 2017 Carl Moyer Guidelines that ensure that funding will be provided only to those projects that achieve emission reductions beyond those required by local, state, or federal requirements or other legally binding documents.[65] Because the FARMER projects relied on in the Amended Valley Incentive Measure [66] are subject to the 2017 Carl Moyer Guidelines, CARB's rationale for finding that the identified Carl Moyer projects achieve surplus emission reductions also applies to the identified FARMER projects.[67]

For all of these reasons, we find that the Amended Valley Incentive Measure achieves ''surplus'' emission reductions—*i.e.,* emission reductions beyond those already credited in the SJV $PM_{2.5}$ Plan.

Comment 2: Earthjustice states that the Valley Incentive Measure does not satisfy the enforceability requirements in section 110(a)(2)(A) of the CAA. Citing the EPA's Memo to Docket for a rulemaking entitled ''State Implementation Plans: Response to Petition for Rulemaking; Finding of Substantial Inadequacy; and SIP Calls to Amend Provisions Applying to Excess Emissions During Periods of Startup, Shutdown, and Malfunction,'' Earthjustice states that to be ''enforceable,'' a measure must be enforceable by the state, the EPA, and citizens. Earthjustice also states that the mere approval of a measure into the SIP does not convert an unenforceable provision into an enforceable one, and that the EPA's SIP rulemaking must explain how the proposed measure can be enforced. According to Earthjustice, the EPA's proposed rule to approve the Valley Incentive Measure has not provided a legally defensible analysis of how this rule is enforceable.

Response 2: We agree with Earthjustice's statement that the mere approval of a measure into the SIP does not convert an unenforceable provision into an enforceable one, but we disagree with Earthjustice's claim that CARB's commitments in the Valley Incentive Measure are not enforceable. We explain below how the EPA and citizens may enforce the provisions of CARB's SIP commitments in the Amended Valley Incentive Measure. We respond to Earthjustice's more specific comments concerning enforceability in our responses to comments 3 through 12. We note that our evaluation here is limited to CARB's commitments in the Amended Valley Incentive Measure and that the EPA will review each incentive-based control measure submitted by a state on a case-by-case basis, following notice-and-comment rulemaking, to determine whether the applicable requirements of the Act are met.

Under CAA section 110(a)(2)(A), SIPs must include enforceable emission limitations and other control measures, means or techniques necessary to meet the requirements of the Act, as well as timetables for compliance. Similarly, section 172(c)(6) provides that nonattainment area SIPs must include enforceable emission limitations and such other control measures, means or techniques as may be necessary or appropriate to provide for attainment of the NAAQS by the applicable attainment date.

Control measures, including commitments in SIPs, are enforced through CAA section 304(a), which provides for citizen suits to be brought against any ''person,'' including a state,[68] who is alleged ''to be in violation of . . . an emission standard or limitation. . . .'' ''Emission standard or limitation'' is defined in subsection (f) of section 304.[69] As observed in *Conservation Law Foundation, Inc.* v. *James Busey et al.,* 79 F.3d 1250, 1258 (1st Cir. 1996):

> Courts interpreting citizen suit jurisdiction have largely focused on whether the particular standard or requirement plaintiffs sought to enforce was sufficiently specific. Thus, interpreting citizen suit jurisdiction as limited to claims ''for violations of specific provisions of the act or specific provisions of an applicable implementation plan,'' the Second Circuit held that suits can be brought to enforce specific measures, strategies, or commitments designed to ensure compliance with the NAAQS, but not to enforce the NAAQS directly. See, *e.g., Wilder,* 854 F.2d at 613–14. Courts have repeatedly applied this test as the linchpin of citizen suit jurisdiction. See, *e.g., Coalition Against Columbus Ctr.* v. *City of New York,* 967 F.2d 764, 769–71 (2d Cir. 1992); *Cate* v. *Transcontinental Gas Pipe Line Corp.,* 904 F. Supp. 526, 530–32 (W.D. Va. 1995); *Citizens for a Better Env't* v. *Deukmejian,* 731 F. Supp. 1448, 1454–59 (N.D. Cal.), modified, 746 F. Supp. 976 (1990).

Thus, courts have found that the citizen suit provision cannot be used to enforce the aspirational goal of attaining the NAAQS but can be used to enforce specific strategies to achieve that goal.[70]

SIP control measures and commitments may also be enforced by the EPA under section 113(a)(1) of the Act, which authorizes the EPA to issue notices and compliance orders, assess administrative penalties, and bring civil actions against any ''person,'' including a state, who ''has violated or is in

[63] Ca. HSC, Division 26, Part 5, Chapter 9, Article 3, section 44281(b) (prohibiting Carl Moyer funding for an otherwise qualified project if it is ''required by any local, state, or federal statute, rule, regulation, memoranda of agreement or understanding, or other legally binding document, except that an otherwise qualified project may be funded even if the [SIP] assumes that the change in equipment, vehicles, or operations will occur, if the change is not required by a statute, regulation, or other legally binding document in effect as of the date the grant is awarded'').

[64] Demonstration, 19.

[65] Demonstration, 19–21.

[66] The Valley Incentive Measure relies on FARMER projects for off-road diesel agricultural equipment post-inspected from September 1, 2018 to December 31, 2023. TSD, 16.

[67] Demonstration, 43–45. See also TSD, 16–17 (noting that the EPA's evaluation of the 2017 Carl Moyer Guidelines applies equally to the FARMER projects identified in the Valley Incentive Measure).

[68] CAA section 302(e) (defining ''person'' to include a State or political subdivision thereof).

[69] Section 304(f) of the CAA defines ''emission standard or limitation,'' in relevant part, to mean ''a schedule or timetable of compliance'' which is in effect under the Act ''or under an applicable implementation plan.'' Section 302(p) of the Act defines ''schedule and timetable of compliance'' to mean ''a schedule of required measures including an enforceable sequence of actions or operations leading to compliance with an emission limitation, other limitation, prohibition, or standard.'' Section 302(q) of the Act defines ''[a]pplicable implementation plan,'' in relevant part, as ''the portion (or portions) of the implementation plan, or most recent revision thereof, which has been approved under section 110 of [title I of the Act] . . . and which implements the relevant requirements of [the Act].''

[70] See also *Committee for a Better Arvin, et al.* v. *EPA,* 786 F.3d 1169, 1181 (9th Cir. 2015) (finding that California's commitments to propose and adopt emission control measures and to achieve aggregate emission reductions are enforceable ''emission standards or limitations'' under the CAA).

violation of any requirement or prohibition of an applicable implementation plan. . . .'' [71]

CARB's commitments in the Amended Valley Incentive Measure are set forth on pages 7–12 of CARB Resolution 19–26 (December 12, 2019), as amended and clarified by the Technical Corrections Document and the 2021 Clarification Document.[72] We refer to these submissions collectively as the ''Amended Valley Incentive Measure.'' The portions of CARB's commitments in the Amended Valley Incentive Measure that we are approving in this rule include seven key components, as summarized below:

(1) Commitments to monitor the District's implementation of estimated numbers of Carl Moyer and FARMER projects in accordance with specified portions of the relevant program guidelines;

(2) commitments to achieve specific amounts of NO_X and $PM_{2.5}$ emissions reductions in the San Joaquin Valley by 2024 and 2025 through implementation of the identified types of incentive projects or through adoption and submission of substitute control measures (hereafter ''tonnage commitments'');

(3) commitments to submit reports to the EPA by May 15 each year from 2021 through 2025, each of which must include specific information about the incentive projects funded through the previous year and state CARB's determination of whether the identified projects are expected to fulfill the NO_X and $PM_{2.5}$ tonnage commitments (hereafter ''annual demonstration reports'');

(4) commitments to make the annual demonstration reports available on CARB's website and to the public upon request, by May 15 of each year from 2021 to 2030, and to maintain all annual demonstration reports through December 31, 2030;

(5) commitments to provide to the public, upon request, certain project-specific documents relied upon in the preparation of CARB's annual demonstration reports, including project applications, grant contracts, and inspection-related documents;

(6) if CARB is relying on any substitute incentive projects to fulfill the tonnage commitments, commitments to confirm that all such substitute incentive projects are subject to the program criteria identified in the Amended Valley Incentive Measure and to provide specific information about each substitute project in the relevant annual demonstration report(s); and

(7) commitments to adopt and submit substitute measures or rules to the EPA by a date certain, if the EPA determines that information submitted by CARB is insufficient to demonstrate that the emission reductions necessary to fulfill the tonnage commitments for a given year will occur on schedule.[73]

CARB states in the Demonstration that ''CARB is the responsible party for enforcement of this measure and is responsible for achieving the emission reductions from this measure,'' thus expressing CARB's decision to voluntarily commit itself to fulfilling the tonnage commitment and to being held accountable for failure to fulfill this commitment.[74]

Upon the EPA's approval of these commitments into the SIP under CAA section 110, the commitments will become federally enforceable requirements of an ''applicable implementation plan'' as defined in CAA section 302(q). Therefore, as discussed below, both citizens and the EPA may enforce these commitments under CAA sections 304(a)(1) and 113(a)(1), respectively. We describe each enforceable component of the Amended Valley Incentive Measure below.

First, the Amended Valley Incentive Measure obligates CARB to monitor the District's implementation of estimated numbers of Carl Moyer and FARMER projects in accordance with specified portions of the relevant program guidelines.[75] The Carl Moyer and FARMER program guidelines [76] enable CARB to carry out these oversight responsibilities by requiring, among other things, that air districts (1) maintain, for specified periods of time, all project-related documentation obtained from participating sources and through the air district's on-site project inspections; [77] (2) make such documents available to CARB staff during CARB's periodic ''incentive program reviews'' and upon request; [78] (3) submit a certified ''yearly report'' to CARB containing specific information about funded projects, including information sufficient to calculate emission reductions and cost-effectiveness for source categories where required; [79] and

[71] CAA section 113(a)(1)–(2) (establishing EPA's SIP enforcement authorities), section 302(e) (defining ''person'' to include a state or political subdivision thereof), and section 302(q) (defining ''applicable implementation plan'' to include the portion(s) of the implementation plan approved under CAA section 110 that implement relevant CAA requirements).

[72] CARB Resolution 19–26, ''San Joaquin Valley Agricultural Incentive Measure'' (December 12, 2019), 7–12, and Executive Order S–20–031, ''Adoption and Submittal of Technical Clarifications and Typographical Error Corrections to the San Joaquin Valley Agricultural Equipment Incentive Measure'' (November 23, 2020) (hereafter ''Technical Corrections Document'').

[73] Id. We use the shorthand term ''insufficiency finding'' to refer to a determination by the EPA that information submitted by CARB is insufficient to demonstrate that CARB will fulfill the tonnage commitment on schedule. An insufficiency finding by the EPA triggers CARB's obligation, under the terms of paragraphs A.5 and A.6 of CARB Resolution 19–26, to adopt and submit substitute measures or rules that address any shortfall in required emission reductions.

[74] Demonstration, 29 and 52.

[75] CARB Resolution 19–26, sections B and D. CARB is required under California law to monitor air district implementation of Carl Moyer projects to ensure compliance with the applicable guidelines. California Health & Safety Code (Ca. HSC) section 44291(d) (requiring CARB to ''monitor district programs to ensure that participating districts conduct their programs consistent with the criteria and guidelines established by the state board and the commission pursuant to this chapter'').

[76] All FARMER projects that CARB relies on to comply with the Valley Incentive Measure are subject to the 2017 Carl Moyer Guidelines, future approved guidelines, and current and future program advisories and mail-outs, except as modified by CARB. TSD, 16–17. See also Demonstration, 43–45 and 2018 FARMER Guidelines, 17–18. Therefore, references herein to the 2017 Carl Moyer Guidelines apply to both Carl Moyer projects and FARMER projects. Should CARB revise the 2018 FARMER Guidelines at any point before May 15, 2025, it will be obligated under paragraph D.2 of CARB Resolution 19–26 to provide, in the annual demonstration report for the relevant year, a ''description of any changes to the 2018 FARMER Guidelines and their related impacts on program integrity.'' TSD, 17 (referencing Valley Incentive Measure, 11 (CARB Resolution 19–26, para. D.2)).

[77] The Carl Moyer Guidelines require that each implementing air district maintain a file for each funded project (a ''project file'') that includes, among other things, a copy of the application, a copy of the executed project contract and any related amendments, photographic and other documentation of the baseline (replaced) engine, vehicle, or equipment, and photographic and other documentation of the new engine, vehicle, or equipment. See, *e.g.,* 2011 Carl Moyer Guidelines, Part I, Chapter 3, Section W (''Application Evaluation and Project Selection''), para. 6; Section V (''Minimum Project Application Requirements''); Section Y (''Minimum Contract Requirements''); Section Z (''Project Pre-Inspection''); and Section AA (''Project Post-Inspection''). Air districts must generally maintain each project file for at least three years after the end of the contract term. Id. at Section U (''ARB Program Oversight''), para. 5.A. See also similar provisions in 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 3, Section S (''Requirements for Project Applications''), para. 2; Section T (''Application Evaluation and Project Selection''), paras. 1 and 8; Section V (''Minimum Contract Requirements''); Section W (''Project Pre-Inspection''); and Section X (''Project Post-Inspection'').

[78] See, *e.g.,* 2011 Carl Moyer Guidelines, Part I, Chapter 3, Section R (''Yearly Report''), para. 3.C (requiring that air districts make project-specific documents available to CARB upon request) and Section U (''ARB Program Oversight''), para. 5.A (requiring that air districts make project files readily available to CARB staff during program reviews) and 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 3, Section M (''Yearly Report''), para. 4 and Section R (''Incentive Program Review''), para. 5.

[79] See, *e.g.,* 2011 Carl Moyer Guidelines, Part I, Chapter 3, Section R (''Yearly Report'') and 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 3, Section M (''Yearly Report'').

(4) allow CARB and its designees to conduct fiscal audits and to inspect project engines, vehicles, and/or equipment and associated records during the contract term.[80] The Carl Moyer Guidelines also specifically identify types of actions on the part of the implementing air district that CARB may treat as violations of program requirements—*e.g.,* misuse of Carl Moyer program funds to fund ineligible projects and insufficient, incomplete, or inaccurate project documentation [81]—and authorize CARB to enforce the terms of a project contract at any time during the contract term to ensure that emission reductions are achieved.[82] If CARB fails to document in each annual demonstration report the steps it has taken to exercise these monitoring responsibilities, that failure would constitute a violation of the SIP commitment. See Response 4.

Second, the Amended Valley Incentive Measure obligates CARB to achieve, by December 31, 2023, a total of 4.83 tpd of reductions in NO_X emissions and 0.24 tpd of reductions in $PM_{2.5}$ emissions from the 2024 baseline inventory in the 2018 $PM_{2.5}$ Plan through implementation of (a) the Carl Moyer and FARMER projects identified in sections B and D of the commitment, (b) substitute incentive projects consistent with paragraph A.4 of the commitment, or (c) other substitute control measures adopted and submitted to the EPA in accordance with paragraph A.5 of the commitment.[83] If CARB fails to achieve these amounts of NO_X and $PM_{2.5}$ emission reductions by December 31, 2023, through implementation of incentive projects or substitute control measures that meet the identified criteria, that failure would constitute a violation of the SIP commitment.

Similarly, the Amended Valley Incentive Measure obligates CARB to achieve, by December 31, 2024, a total of 4.46 tpd of reductions in NO_X emissions and 0.26 tpd of reductions in $PM_{2.5}$ emissions from the 2025 baseline inventory in the 2018 $PM_{2.5}$ Plan, through implementation of (a) the Carl Moyer and FARMER projects identified in sections B and D of the commitment, (b) substitute incentive projects consistent with paragraph A.4 of the commitment, or (c) other substitute control measures adopted and submitted in accordance with paragraph A.6 of the commitment.[84] If CARB fails to achieve these amounts of NO_X and $PM_{2.5}$ emission reductions by December 31, 2024, through implementation of incentive projects or substitute control measures that meet the identified criteria, that failure would constitute a violation of the SIP commitment.

Third, the Amended Valley Incentive Measure obligates CARB to submit annual demonstration reports to the EPA by May 15 each year from 2021 through 2025, each of which must contain specific information about the incentive projects funded through the previous year and state CARB's determination of whether the identified projects are projected to fulfill the NO_X and $PM_{2.5}$ tonnage commitments for 2024 and 2025.[85] If CARB fails to timely submit an annual demonstration report containing all of the information listed in paragraphs A.3, B.2 and D.2 of the Amended Valley Incentive Measure, that failure would constitute a violation of the SIP commitment.

Fourth, the Amended Valley Incentive Measure obligates CARB to make the annual demonstration reports available on CARB's website and to the public upon request, by May 15 of each year from 2021 to 2030, and to maintain all annual demonstration reports through December 31, 2030.[86] If CARB fails to make any of these reports available on its website or available upon request by May 15 of the relevant year, that failure would constitute a violation of the SIP commitment.

Fifth, the Amended Valley Incentive Measure obligates CARB to provide to any requestor, beginning May 15, 2021, and through 2029, certain project-specific documents relied upon in the preparation of CARB's annual demonstration reports, including project applications, grant contracts, and inspection-related documents.[87] If CARB fails to provide any of these project records within a reasonable period after receiving a request, that failure would constitute a violation of the SIP commitment.

Sixth, the Amended Valley Incentive Measure obligates CARB to provide, in each annual demonstration report, confirmation that any substitute incentive projects that it relies on to fulfill the tonnage commitments are subject to the program criteria identified in paragraph B.1 or D.1 of the commitment and to provide specific information about each substitute project.[88] If CARB fails to submit such information in any annual demonstration report that documents CARB's reliance on substitute incentive projects, that failure would constitute a violation of the SIP commitment.

Finally, if the EPA determines by August 1, 2022, that information submitted by CARB is insufficient to demonstrate that the emission reductions necessary to fulfill the 2024 tonnage commitments will occur on schedule, the Amended Valley Incentive Measure obligates CARB to adopt and submit to the EPA, no later than September 1, 2023, substitute measures or rules that will achieve emission reductions addressing the shortfall as expeditiously as practicable and no later than January 1, 2024.[89] If CARB fails to adopt and submit timely substitute measures or rules sufficient to address a shortfall in required emission reductions, that failure would constitute a violation of the SIP commitment.

Similarly, if the EPA determines by August 1, 2023, that information submitted by CARB is insufficient to demonstrate that the emission reductions necessary to fulfill the 2025 tonnage commitments will occur on schedule, the Amended Valley Incentive Measure obligates CARB to adopt and submit to the EPA, no later than September 1, 2024, substitute measures or rules that will achieve emission reductions addressing the shortfall as expeditiously as practicable and no later than January 1, 2025.[90] If CARB fails to adopt and submit timely substitute measures or rules sufficient to address a shortfall in required emission

[80] See, *e.g.,* 2011 Carl Moyer Guidelines, Part I, Chapter 3, Section Y (''Minimum Contract Requirements''), para. 10 and 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 3, Section V (''Minimum Contract Requirements''), para. 10.

[81] 2011 Carl Moyer Guidelines, Part I, Chapter 3, Section U (''Program Non-Performance'') and 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 3, Section Q (''Program Nonperformance'').

[82] 2011 Carl Moyer Guidelines, Part I, Chapter 3, Section Y (''Minimum Contract Requirements'') and 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 3, Section V (''Minimum Contract Requirements''), para. 11 (''Repercussions for Nonperformance'').

[83] CARB Resolution 19–26, para. A.1.

[84] Id. at para. A.2.

[85] Id. at paras. A.3., B.2., and D.2.

[86] Id. at paras. B.3. and D.3. CARB's commitment is to submit annual demonstration reports by May 15 of each year from 2021 to 2025, and thereafter to maintain all such reports through December 31, 2030 so that they are available to the public upon request.

[87] CARB Resolution 19–26, paras. B.5 and D.5 (added by Technical Corrections Document, paras. 7 and 11).

[88] CARB Resolution 19–26, para. A.4. For example, if CARB chooses to monitor implementation of 2,500 Carl Moyer projects by 2024 (109 more than its estimate of 2,391 such projects, see para. B.1 of CARB Resolution 19–26) and to monitor 1,900 FARMER projects by 2024 (112 less than its estimate of 2,012 such projects, see para. D.1 of CARB Resolution 19–26), CARB must identify the additional 109 Carl Moyer projects as ''substitute projects'' in the relevant annual demonstration report(s) and provide all of the information required by para. A.4 of CARB Resolution 19–26 pertaining to these projects.

[89] Id. at para. A.5.

[90] Id. at para. A.6.

reductions, that failure would constitute a violation of the SIP commitment.

This series of actions mandated by the Amended Valley Incentive Measure constitutes a specific enforceable strategy for achieving specific amounts of NO_X and $PM_{2.5}$ reductions by the beginning of 2024 and 2025. The fact that CARB may meet its SIP commitments by adopting measures that are not specifically identified in the SIP, or through one of several available techniques, does not render the requirement to achieve the emissions reductions unenforceable.[91]

For all of these reasons, we conclude that CARB's commitments in the Amended Valley Incentive Measure to monitor and report annually on the implementation of specific types of incentive projects, to achieve specified tonnages of NO_X and $PM_{2.5}$ emission reductions from these projects or substitute measures, to make the annual demonstration reports and related documentation available to the public, and to adopt and submit substitute control measures where necessary to address an emission reduction shortfall identified by the EPA, constitute appropriate means, techniques, or schedules for compliance under sections 110(a)(2)(A) and 172(c)(6) of the Act.

Comment 3: Earthjustice states that citizens and the EPA can only enforce ''violations,'' and that the EPA must describe what would constitute a violation of the SIP provisions being approved here. Citing section 304(a)(1) of the CAA, Earthjustice states that citizens can commence civil actions for violations of emission standards or limitations or orders issued by the EPA or a state with respect to such standards or limitations. Additionally, citing section 113(a)(1) of the Act, Earthjustice states that the EPA can enforce a violation of any requirement or prohibition of an applicable implementation plan. Earthjustice notes the EPA's statement in the TSD that to be enforceable, program violations must be defined, and asserts that the EPA must explain where in the Valley Incentive Measure such definitions are provided. According to Earthjustice, the EPA ''suggests that EPA and citizens can enforce the commitments to achieve and report on emission reductions'' but does not define what exactly would constitute a violation.

Response 3: We identify in Response 2 the types of violations of the commitments that could provide the basis for an enforcement action by the EPA or by citizens under section 113(a)(1) or 304(a)(1) of the CAA, respectively. As explained in Response 2, CARB's commitments constitute a specific enforceable strategy for achieving specific amounts of NO_X and $PM_{2.5}$ reductions on a fixed schedule and, upon approval into the SIP, become requirements of an ''applicable implementation plan'' as defined in CAA section 302(q). Although the Amended Valley Incentive Measure does not specifically define potential violations of the commitments, we find that it describes each of the actions that CARB has committed to undertake in sufficient detail to enable the EPA and the public to determine whether and when a violation has occurred. Accordingly, these commitments are enforceable by citizens under CAA section 304(a)(1) and by the EPA under CAA section 113(a)(1).

Comment 4: Earthjustice states that CARB's commitment to ''monitor'' District and NRCS implementation of projects in accordance with the Carl Moyer program, FARMER and NRCS guidelines is a ''vague and unenforceable commitment.'' Earthjustice asks what would constitute a violation, and how one could prove that CARB is not monitoring implementation in accordance with the guidelines. Earthjustice asserts that there is no means of measuring or independently verifying compliance because there is no reporting requirement and no deadline. Additionally, Earthjustice claims that the reference to ''an estimated 5,446 . . . replacement projects'' in CARB's commitment ''undermines the very notion that CARB even know[s] what or how many projects to monitor.'' Earthjustice notes that CARB cannot receive detailed compliance reports on projects under the NRCS program and can only request ''representative samples of the compliance-related documentation'' used by the NRCS to compile anonymized annual reports. Earthjustice asserts that there is no way to enforce this monitoring obligation, and even if one could, there is no way for CARB to actually fulfill its obligations because it has no monitoring authority itself.

Response 4: We disagree with these comments. CARB's commitments to monitor the District's implementation of projects in accordance with the Carl Moyer Guidelines and FARMER Guidelines are enforceable through specific provisions in the Amended Valley Incentive Measure that require CARB to report annually on, among other things, the incentive projects it is relying on to achieve emission reductions and the actions that CARB or the District has taken to ensure that these projects comply with the applicable guidelines and program criteria. See Response 2.

Specifically, the Amended Valley Incentive Measure obligates CARB to identify, in each annual demonstration report submitted to the EPA by May 15 of each year from 2021 through 2025, those projects funded through the previous year that CARB is relying on to achieve the tonnage commitments for 2024 and 2025. CARB must identify each of these projects ''by project identification number, project life and implementation date, description of both baseline and new equipment sufficient to independently calculate emission reductions, applicable incentive program guideline, and quantified emission reductions.'' [92] Additionally, each annual demonstration report must include supporting documentation for the reported project information, describe any changes to the applicable guidelines or program criteria, and describe the implementing agency's actions to review selected projects for compliance with these criteria.[93]

For Carl Moyer projects, the Amended Valley Incentive Measure obligates CARB to include in each annual demonstration report a ''description of any changes to the 2011 and 2017 Moyer Guidelines and their related impacts on program integrity'' and ''a description of CARB and the District's actions during the prior year to monitor selected projects for compliance with Moyer Program requirements.'' [94] Similarly, for FARMER projects, CARB must include in each annual demonstration report a ''description of

[91] *Citizens for a Better Environment* v. *Deukmejian,* 731 F. Supp. 1448, 1454–59 (N.D. Cal.) (''the basic commitment to adopt and implement additional measures, should the identified conditions occur, constitutes a specific strategy, fully enforceable in a citizens action, although the exact contours of those measures are not spelled out''), modified, 746 F. Supp. 976 (1990) (holding state and district liable for failing to satisfy SIP commitment).

[92] CARB Resolution 19–26, para. A.3. For Carl Moyer and FARMER projects, the ''project life'' begins on the purchase date of the new equipment and is the period during which the project is under contract. Email dated February 13, 2020, from Austin Hicks (CARB) to Rynda Kay (EPA Region IX), Subject: ''RE: Follow-up questions on the Valley Incentive Measure.'' We understand the ''implementation date'' to mean the post-inspection date, which is the date on which the District verifies that the old equipment has been destroyed and that the new equipment has been purchased, is operational, and is the same equipment that was used in the emission reduction calculations. 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 3, Section V (''Minimum Contract Requirements'') and Section X (''Project Post-Inspection'').

[93] CARB Resolution 19–26, paras. B.2, C.3, and D.2.

[94] Id. at para. B.2.

any changes to the 2018 FARMER Guidelines and their related impacts on program integrity'' and ''a description of CARB's and the District's actions during the prior year to monitor selected projects for compliance with FARMER Program requirements.'' [95] Finally, for both incentive programs, if the total number of implemented projects is less than the estimated number of projects identified in paragraph B.1 or D.1 of CARB Resolution 19–26 (as applicable), CARB's annual demonstration report must confirm that any substitute projects relied on to fulfill the tonnage commitments are subject to the program criteria identified in paragraph B.1 or D.1 and provide, for each substitute project, all of the information required in paragraph B.2.c and D.2.c.[96]

These provisions ensure that CARB's annual demonstration reports will contain both the project-specific information needed to independently calculate the emission reductions that CARB attributes to each project and the programmatic information needed to determine whether CARB and the District are taking appropriate steps to ensure that the identified projects comply with the applicable guidelines and program criteria.[97] If CARB's annual demonstration report for a given year fails to identify the project-specific information described in paragraphs A.3, B.2, or D.2 of CARB Resolution 19–26, as amended by the Technical Corrections Document, or to document the steps it has taken to verify the District's compliance with the applicable guidelines and program criteria, the EPA or citizens may bring an enforcement action against CARB for violating its monitoring and reporting obligations in the Amended Valley Incentive Measure.

Both CARB and the District are directly responsible for ensuring that the Carl Moyer program is implemented in accordance with State law.[98] As explained in Response 2, the Carl Moyer program guidelines enable CARB to monitor the implementing air district's compliance with the applicable program guidelines by requiring, among other things, that air districts maintain compliance-related documentation, make such documents available to CARB staff upon request, submit certified ''yearly reports'' to CARB containing specific information about funded projects, and allow CARB and its designees to inspect project engines, vehicles, and/or equipment and associated records during the contract term.[99] The Carl Moyer program guidelines also specifically identify types of actions on the part of the implementing air district that CARB may treat as program violations and authorize CARB to enforce the terms of a project contract.[100] If CARB fails to document in each annual demonstration report the steps it has taken to exercise these monitoring responsibilities, that failure would constitute a violation of the SIP commitment.

As Earthjustice correctly notes, we stated in our TSD that the Valley Incentive Measure obligates CARB to monitor an ''estimated'' total of 5,446 off-road diesel agricultural equipment replacement projects in accordance with the Carl Moyer, FARMER, and NRCS programs and their respective guidelines.[101] Earthjustice claims that this reference to an ''estimated'' number of projects ''undermines the very notion that CARB even know[s] what or how many projects to monitor.'' This comment, however, appears to be based on a misunderstanding of the purpose of these provisions of the commitment. CARB's primary obligations under the Amended Valley Incentive Measure are to (1) monitor District implementation of estimated numbers of incentive projects in accordance with specified portions of the relevant program criteria, (2) fulfill specific NO_X and $PM_{2.5}$ tonnage commitments through implementation of the identified projects or through adoption and submission of substitute control measures, (3) submit to the EPA, each year from 2021 to 2025, a publicly available annual demonstration report that includes specific information about the projects funded through the previous year, (4) maintain and provide to the public, upon request, the documentation that CARB has relied on to develop the annual demonstration reports, and (5) adopt and submit substitute measures or rules by specific dates, if the EPA determines that information submitted by CARB is insufficient to demonstrate that the identified projects will fulfill the tonnage commitments. See Response 2.

The Amended Valley Incentive Measure does not obligate CARB to ensure implementation of any particular number of projects. The purpose of the project number estimates in paragraphs B.1 and D.1 (and the total project number estimates provided in paragraph A.3) of CARB Resolution 19–26 is to establish reasonable limits on the extent to which CARB may change the list of projects relied upon from year to year, while allowing CARB some flexibility to substitute listed projects with different project types,[102] provided all projects identified in the annual demonstration report satisfy the applicable program criteria [103] and achieve, in the aggregate, the tonnages of emission reductions identified in paragraphs A.1 and A.2 of CARB Resolution 19–26. In this way, the project number estimates enable the EPA and the public to hold CARB responsible for overseeing substantial numbers of projects under both the Carl Moyer and FARMER programs and ensuring that its selected mix of projects ultimately fulfills the tonnage commitments by 2024 and 2025.[104] We

[95] Id. at para. D.2.

[96] CARB Resolution 19–26, paras. B.2.d and D.2.d (requiring that CARB provide ''information consistent with paragraph A.4 pertaining to the substitute incentive projects that will be implemented to achieve the emission reductions specified in [paragraphs] A.1 and A.2''). For example, if CARB chooses to monitor implementation of 2,500 Carl Moyer projects by 2024 (109 more than its estimate of 2,391 such projects, see para. B.1 of CARB Resolution 19–26) and to monitor 1,900 FARMER projects by 2024 (112 fewer than its estimate of 2,012 such projects, see para. D.1 of CARB Resolution 19–26), CARB must identify the additional 109 Carl Moyer projects as ''substitute projects'' in the relevant annual demonstration report(s) and provide all of the information required by paragraph A.4 of CARB Resolution 19–26 pertaining to these projects. Only incentive projects subject to the specific guidelines and program criteria referenced in paragraphs B.1 or D.1 of the Valley Incentive Measure qualify for use as ''substitute projects.''

[97] For Carl Moyer projects, the 2017 Carl Moyer Guidelines specifically require that air districts audit at least five percent of active projects or 20 active projects (whichever is less), including any audits conducted following unsatisfactory annual reporting. 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 3, Section AA (''Air District Audit of Projects''), para. 1.

[98] Ca. HSC section 44291(d) (requiring CARB to ''monitor district programs to ensure that participating districts conduct their programs consistent with the criteria and guidelines established by the state board and the commission pursuant to this chapter''). See also 2011 Carl Moyer Guidelines, Part I, Chapter 1 (''Program Overview'') and 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 1 (''Program Overview'').

[99] See footnotes 76–79, supra.

[100] See footnotes 80 and 81, supra.

[101] TSD, 4. Because we are approving only those portions of the Valley Incentive Measure that pertain to Carl Moyer and FARMER projects, the total estimated number of projects that CARB must monitor under para. A.3.a of CARB Resolution 19–26 is 4,403 (5,446 − 1,043), and the total estimated number of projects that CARB must monitor under para. A.3.b of the resolution is 3,980 (4,723 − 743). CARB Resolution 19–26, paras. A.3 and C.2.

[102] See fn. 87, supra (explaining how CARB may substitute a small number of Carl Moyer projects for FARMER projects).

[103] CARB Resolution 19–26, para. A.4.

[104] The project number estimates also enabled the EPA and the public to evaluate the tonnage commitments in the Valley Incentive Measure and to determine whether CARB could reasonably be expected to achieve the necessary emission reductions through the identified project types. TSD, 26–28 (explaining the EPA's conclusion that it is ''reasonable to expect that the implementation of projects under these three incentive programs will achieve the full amount of NO_X and $PM_{2.5}$ emission reductions that CARB has committed to achieve in the Valley Incentive Measure'').

therefore disagree with Earthjustice's claim that the project number estimates ''undermine'' CARB's ability to carry out its monitoring obligation.

Additionally, as explained in Response 2, CARB is obligated to achieve 4.83 and 4.46 tpd of NO_X emission reductions by December 31, 2023 and December 31, 2024, respectively, and to achieve 0.24 and 0.26 tpd of $PM_{2.5}$ emission reductions by December 31, 2023 and December 31, 2024, respectively, either through implementation of the identified agricultural equipment replacement projects or through substitute measures adopted and submitted in accordance with the deadlines specified in paragraphs A.5 and A.6 of CARB Resolution 19–26.[105] Thus, although CARB is not specifically obligated to ensure that certain numbers of incentive projects are implemented or to achieve the required NO_X or $PM_{2.5}$ emission reductions through incentive projects, CARB is obligated to monitor substantial numbers of the specified types of incentive projects for the purpose of determining whether those projects will achieve the necessary amounts of NO_X and $PM_{2.5}$ emission reductions by December 31, 2023, and December 31, 2024, in the San Joaquin Valley. If CARB fails to adequately document its bases for finding that the identified incentive projects have fulfilled the tonnage commitments, CARB must adopt and submit substitute measures sufficient to address the shortfall.[106]

Comment 5: Earthjustice states that nothing in CARB's commitment to achieve 5.9 tpd of NO_X and 0.3 tpd of $PM_{2.5}$ emission reductions by December 31, 2023, or its commitment to achieve 5.1 tpd of NO_X and 0.3 tpd of $PM_{2.5}$ by December 31, 2024, specifies where these emission reductions must come from or where they must occur. Earthjustice claims that nothing specifies whether these reductions must be the result of some action by the agencies or merely the result of favorable economic conditions, and that CARB has relied on the latter in the past to claim compliance with similar ''commitments.'' Earthjustice further claims that there is no way for the EPA or citizens to look at the entire emissions inventory for the San Joaquin Valley on December 31, 2024, and determine whether CARB has achieved this emission reduction, and that even if overall emissions increase between 2019 and 2022, CARB could still claim that but for some unspecified reason, the total NOx emissions would have been 5.9 tpd higher. Earthjustice argues that because there is no way to prove that CARB has not achieved the NO_X and $PM_{2.5}$ reductions, the commitment fails to define any possible violation and is not practicably enforceable.

Response 5: We identify in Response 2 the types of violations of the commitments that may provide the basis for an enforcement action by the EPA or by citizens under section 113(a)(1) or 304(a)(1) of the CAA, respectively. As explained in Response 2, CARB's commitments constitute a specific enforceable strategy for achieving specific amounts of NO_X and $PM_{2.5}$ reductions on a fixed schedule and, upon approval into the SIP, become requirements of an ''applicable implementation plan'' as defined in CAA section 302(q). Accordingly, these commitments are enforceable by citizens under CAA section 304(a)(1) and by the EPA under CAA section 113(a)(1).

Earthjustice's characterization of CARB's commitments is incorrect in several respects. First, with respect to CARB's commitments to achieve specific amounts of NO_X and $PM_{2.5}$ reductions by December 31, 2023, and by December 31, 2024, Earthjustice claims incorrectly that the commitments do not specify where these emission reductions must come from or where they must occur. The Amended Valley Incentive Measure specifies that CARB must achieve emission reductions through implementation of one or both of the following types of measures: (1) Incentive projects implemented in accordance with specified program criteria, and/or (2) substitute control measures adopted and submitted to the EPA by specified deadlines.[107] It also makes clear that these emission reductions must occur in the San Joaquin Valley.[108]

Second, Earthjustice claims incorrectly that nothing in the commitment ''specifies whether [the emission reductions] must be the result of some action by the agencies or merely the result of favorable economic conditions, which is exactly how CARB has claimed compliance with similar 'commitments' in the past.'' By its terms, the Amended Valley Incentive Measure obligates CARB to ''achieve'' the identified emission reductions by December 31, 2023, and December 31, 2024, either by confirming implementation of identified incentive projects in accordance with specific guidelines and program criteria or by adopting and submitting to the EPA substitute control measures that achieve equivalent emission reductions by December 31, 2023, or December 31, 2024, as applicable. In the interpretative statements preceding these commitments and in the Demonstration, CARB recognizes its obligation to ''provide a publicly-enforceable commitment to achieve the reductions'' [109] and confirms that the Amended Valley Incentive Measure is enforceable because it ''ensur[es] that actions required of project grantees are independently verifiable, program violations are defined, those liable can be identified, penalties or corrective action may occur and citizens have access to all emissions-related information obtained from participating sources.'' [110] Nowhere in the Amended Valley Incentive Measure or in CARB's interpretative statements does CARB indicate that favorable economic conditions may suffice to achieve the aggregate tonnage commitments.

We note that in prior EPA actions approving aggregate tonnage commitments from CARB, the EPA has rejected claims that ''actual emission decreases'' resulting from an economic recession or other circumstances may

[105] CARB Resolution 19–26, paras. A.1, A.2, A.5, and A.6.

[106] Id.

[107] CARB Resolution 19–26, paras. A.1, A.2, A.5, and A.6.

[108] Id. at A.1, A.2 (requiring CARB to achieve emission reductions from specified baseline inventories ''in the 2018 $PM_{2.5}$ Plan, as detailed in the Valley State SIP Strategy . . .''). The 2018 $PM_{2.5}$ Plan and Valley State SIP Strategy together constitute California's Serious area plan for attaining the 2006 $PM_{2.5}$ NAAQS in the San Joaquin Valley. 85 FR 44192 (July 22, 2020). See also CARB Resolution 19–26, 3 (''CARB staff prepared the [Valley Incentive Measure] to demonstrate that it meets the U.S. EPA SIP measure requirements to achieve emission reductions from the incentivized turnover of agricultural equipment in the [San Joaquin] Valley''). The 2018 $PM_{2.5}$ Plan and Valley State SIP Strategy also contain California's Serious area plan for attaining the 2012 $PM_{2.5}$ NAAQS in the San Joaquin Valley. CARB Resolution 19–1 (January 24, 2019) (adopting 2018 $PM_{2.5}$ Plan and 2016 Moderate Plan for San Joaquin Valley), CARB Resolution 18–49 (October 25, 2018) (adopting Valley State SIP Strategy), and CARB, ''Staff Report, Review of the San Joaquin Valley 2018 Plan for the 1997, 2006, and 2012 $PM_{2.5}$ Standards,'' release date December 21, 2018 (''CARB Staff Report''), 5–7.

[109] CARB Resolution 19–26, 3 (''Whereas, for incentive-based measures, U.S. EPA also requires the State to . . . provide a publicly-enforceable commitment to achieve the reductions'').

[110] Id. at 4–6 (whereas clauses concerning enforceability of emission reductions achieved through Carl Moyer and FARMER projects). Similarly, CARB states in the Demonstration that ''the District and CARB will report and track to ensure that the Valley Incentive Measure . . . delivers the reductions needed,'' that ''[t]he public will be able to calculate the emission reductions using widely available methods and assumptions documented in this report, and in a manner that can be replicated,'' and that ''U.S. EPA and the public will be able to determine whether emission reductions attributed to a project adequately covers the period for which those reductions are credited in a SIP. . . .'' Demonstration, 4.

count towards meeting the commitments and made clear that the only permissible means for achieving the required emission reductions is through notice-and-comment rulemaking procedures leading to the adoption and implementation of enforceable control measures.[111]

Third, Earthjustice suggests, incorrectly, that the EPA and citizens would have to look at the entire emissions inventory for the San Joaquin Valley on December 31, 2024 (or December 31, 2023), to determine whether CARB has achieved the emission reductions required in the Valley Incentive Measure. For the reasons stated in this response and earlier in Response 2, it is not necessary to review an emissions inventory to determine whether CARB has achieved the required reductions. The Amended Valley Incentive Measure obligates CARB to provide, in each annual demonstration report submitted to the EPA from May 2021 through May 2025, detailed information about each incentive project that CARB is relying on to achieve the necessary emission reductions, including identification and descriptions of both the old (replaced) and new equipment sufficient to independently calculate emission reductions.[112] Each of these annual demonstration reports must be readily available to the public upon submission to the EPA and remain available on CARB's website through December 31, 2030.[113] If CARB's 2024 annual demonstration report (which is due May 15, 2024) fails to demonstrate that the identified projects have achieved 4.83 tpd of NO_X emission reductions and 0.24 tpd of $PM_{2.5}$ emission reductions from the 2024 baseline inventory in the 2018 $PM_{2.5}$ Plan, citizens may sue CARB for violating its SIP commitment. Likewise, if CARB's 2025 annual demonstration report (due May 15, 2025) fails to demonstrate that the identified projects have achieved 4.46 tpd of NO_X emission reductions and 0.26 tpd of $PM_{2.5}$ emission reductions from the 2025 baseline inventory in the 2018 $PM_{2.5}$ Plan, citizens may sue CARB for violating its SIP commitment. The tonnage commitments remain enforceable even if the EPA has not made an insufficiency determination in accordance with paragraph A.5 or A.6 of CARB Resolution 19–26. See Response 7 and Response 9.

Additionally, if the EPA determines by August 1, 2022, that information submitted by CARB is insufficient to demonstrate that the emission reductions necessary to fulfill the 2024 tonnage commitments will occur on schedule, CARB must adopt and submit to the EPA, no later than September 1, 2023, substitute measures or rules that will achieve emission reductions addressing the shortfall as expeditiously as practicable and no later than January 1, 2024.[114] Likewise, if the EPA determines by August 1, 2023, that information submitted by CARB is insufficient to demonstrate that the emission reductions necessary to fulfill the 2025 tonnage commitments will occur on schedule, CARB must adopt and submit to the EPA, no later than September 1, 2024, substitute measures or rules that will achieve emission reductions addressing the shortfall as expeditiously as practicable and no later than January 1, 2025.[115] Any such substitute control measure must be adopted following state rulemaking procedures through which the EPA and the public may track the State's progress in achieving the requisite emissions reductions. We expect CARB to make clear during any such rulemaking that it is proposing the identified measure or rule for purposes of submission to the EPA consistent with its commitment in the Amended Valley Incentive Measure.[116] If, following an insufficiency finding by the EPA, CARB fails to adopt and submit substitute control measures that fully address the identified shortfall in required emission reductions by the relevant deadline, citizens may sue CARB for violating its SIP commitment.

For all of these reasons, we disagree with Earthjustice's claim that the Valley Incentive Measure fails to define any possible violation and is not practicably enforceable.

Comment 6: Earthjustice states that the implication of the rule is that the required emission reductions will come from the replacement of agricultural equipment but that nothing in the measure commits CARB to achieve any such replacements. Earthjustice claims that this rule is ''a transparent attempt to undermine the entire framework of SIP enforceability'' and that the measure is nothing more than ''an open-ended commitment to figure out how to reduce emissions, with no actual enforceable commitment to action.'' Earthjustice states that the purpose of the SIP program is to compel states to identify the specific, enforceable actions they will take to reduce emissions, and that it is not enough for the state to merely promise to reduce emissions somehow and offer that citizens can sue the state if it fails.

Response 6: We agree with Earthjustice's statement that the purpose of the SIP program is to compel states to identify specific, enforceable actions to reduce emissions, but we disagree with the claim that the Valley Incentive Measure is an ''open-ended commitment'' with no enforceable commitment to action.

As explained in Response 2 and Response 4, the Amended Valley Incentive Measure obligates CARB to (1) monitor District implementation of estimated numbers of incentive projects in accordance with specified portions of the relevant program criteria, (2) fulfill specific NO_X and $PM_{2.5}$ tonnage commitments through implementation of the identified projects or through adoption and submission of substitute control measures, (3) submit to the EPA, each year from 2021 to 2025, an annual demonstration report that includes specific information about the projects funded through the previous year, (4) make each annual demonstration report publicly available and available upon request, (5) provide to the public, upon request, certain project-specific documents relied upon in the preparation of CARB's annual demonstration reports, including project applications, grant contracts, and inspection-related documents, and (6) adopt and submit substitute measures or rules by specific dates, if the EPA determines that information submitted by CARB is insufficient to demonstrate that the identified projects will fulfill the tonnage commitments.[117]

Numerous courts interpreting citizen suit jurisdiction under section 304 of the CAA have held that suits can be brought to enforce ''specific measures, strategies, or commitments designed to ensure compliance with the NAAQS,'' though not to enforce the NAAQS directly.[118] As explained in Response 2

[111] See, *e.g.,* 76 FR 69896, 69914–16 (November 9, 2011) (partially approving and partially disapproving $PM_{2.5}$ attainment demonstration for San Joaquin Valley).

[112] CARB Resolution 19–26, paras. A3, B.2 and D.2.

[113] Id. at paras. B.3 and D.3.

[114] Id. at para. A.5.

[115] Id. at para. A.6.

[116] See EPA, Memorandum dated November 22, 2011, from Janet McCabe, Deputy Assistant Administrator, EPA Office of Air and Radiation, to Air Division Directors, EPA Regions 1–10, Attachment B (''Guidelines to States Agencies for Preparing the Public Notices for State Implementation Plan (SIP) Revisions'') (noting that state public notices must state that the regulation or document at issue will be submitted to the EPA for approval into the SIP).

[117] CARB Resolution 19–26 and Technical Corrections Document.

[118] See, *e.g., Conservation Law Foundation, Inc.* v. *James Busey, et. al.,* 79 F. 3d 1250, 1258 and internal citations (1st Cir. 1996).

and Response 4, CARB's commitments constitute a specific enforceable strategy for achieving specific amounts of NO_X and $PM_{2.5}$ reductions on a fixed schedule and, upon approval into the SIP, become requirements of an ''applicable implementation plan'' as defined in CAA section 302(q). Accordingly, these commitments are enforceable by citizens under CAA section 304(a)(1) and by the EPA under CAA section 113(a)(1).

We also disagree with Earthjustice's suggestion that CARB's commitments are unenforceable because CARB has not specifically committed to ''achieve'' or implement any replacements of agricultural equipment. As explained in Response 2 and Response 4, CARB's tonnage commitments must be met through implementation of one or both of the following types of measures: (1) Agricultural equipment replacement projects implemented in accordance with specified program criteria, and/or (2) substitute control measures adopted and submitted to the EPA by specified deadlines.[119] If CARB fails to achieve the specified amounts of NO_X and $PM_{2.5}$ emission reductions by December 31, 2023, or December 31, 2024, through implementation of agricultural equipment replacement projects or substitute control measures, that failure would constitute a violation of the SIP commitment. See Response 2. The fact that CARB may meet its SIP commitments by adopting measures that are not specifically identified in the SIP, or through one of several available techniques, does not render the requirement to achieve the emissions reductions unenforceable.[120]

Comment 7: Earthjustice states that the central obligation of this program is CARB's commitment to rectify shortfalls, but that this obligation is triggered only if the EPA makes a determination. Earthjustice asserts that, without some mechanism for forcing the EPA to make such a determination, citizens cannot enforce CARB's obligation. Furthermore, Earthjustice argues, even if the EPA were to make such a determination, there is no way for the EPA and citizens to prove that CARB had failed to rectify the shortfall because there is no explanation of what action CARB must take. According to Earthjustice, CARB need only point to ''substitute measures or rules'' but these do not need to be new measures, and ''CARB can claim that other regulated sectors reduced emissions more than anticipated for whatever reason.''

Response 7: We agree with Earthjustice's statement that CARB's commitment to rectify shortfalls is dependent on an EPA determination but disagree with the claim that this obligation cannot be enforced by citizens. Additionally, to the extent Earthjustice intended to assert that an insufficiency determination by EPA is necessary to enable citizens to enforce the central obligation in CARB's commitment—*i.e.,* the tonnage commitment—this assertion is incorrect.

As explained in Response 2 and Response 4, the Amended Valley Incentive Measure obligates CARB to (1) monitor District implementation of estimated numbers of incentive projects in accordance with specified portions of the relevant program criteria, (2) fulfill specific NO_X and $PM_{2.5}$ tonnage commitments through implementation of the identified projects or through adoption and submission of substitute control measures, (3) submit to the EPA, each year from 2021 to 2025, an annual demonstration report that includes specific information about the projects funded through the previous year, (4) make each annual demonstration report publicly available and available upon request, (5) provide to the public, upon request, certain project-specific documents relied upon in the preparation of CARB's annual demonstration reports, including project applications, grant contracts, and inspection-related documents, and (6) adopt and submit substitute measures or rules by specific dates, if the EPA determines that information submitted by CARB is insufficient to demonstrate that the identified projects will fulfill the tonnage commitments.[121] The central obligation in these commitments is to fulfill specific NO_X and $PM_{2.5}$ tonnage commitments on a fixed schedule, and the other components of the commitments are designed to ensure that the EPA and citizens can hold CARB responsible for achieving these emission reductions by the specified dates.

Earthjustice correctly notes that the commitment to rectify shortfalls (in paragraphs A.5 and A.6 of CARB Resolution 19–26) is triggered only if the EPA determines that information submitted by CARB is insufficient to demonstrate that the identified projects will fulfill the tonnage commitments. Earthjustice incorrectly claims, however, that there is no way for the EPA or citizens to prove that CARB had failed to rectify a shortfall identified by the EPA because there is no explanation of what action CARB must take. As explained in Response 2 and Response 5, if the EPA determines by August 1, 2022, that information submitted by CARB is insufficient to demonstrate that the emission reductions necessary to fulfill the 2024 tonnage commitments will occur on schedule, CARB must adopt and submit to the EPA, no later than September 1, 2023, substitute measures or rules that will achieve emission reductions addressing the shortfall as expeditiously as practicable and no later than January 1, 2024.[122] Likewise, if the EPA determines by August 1, 2023, that information submitted by CARB is insufficient to demonstrate that the emission reductions necessary to fulfill the 2025 tonnage commitments will occur on schedule, CARB must adopt and submit to the EPA, no later than September 1, 2024, substitute measures or rules that will achieve emission reductions addressing the shortfall as expeditiously as practicable and no later than January 1, 2024.[123]

Contrary to Earthjustice's assertion, CARB cannot satisfy this commitment by simply claiming ''that other regulated sectors reduced emissions more than anticipated for whatever reason.'' By its terms, the commitment is to ''adopt and submit to U.S. EPA . . . substitute measures or rules''—*i.e.,* new or revised prohibitory control measures—that achieve the necessary emission reductions by the specified deadline. Any such substitute control measure must be adopted following state rulemaking procedures through which the EPA and the public may track the State's progress in achieving the requisite emissions reductions.[124] We expect that CARB will make clear during any such rulemaking that it is proposing the identified measure or rule for purposes of submission to the EPA consistent with its commitment in the Amended Valley Incentive Measure.[125]

[119] CARB Resolution 19–26, paras. A.1, A.2, A.5, and A.6.

[120] *Citizens for a Better Environment* v. *Deukmejian,* 731 F. Supp. 1448, 1454–59 (N.D. Cal.) (''the basic commitment to adopt and implement additional measures, should the identified conditions occur, constitutes a specific strategy, fully enforceable in a citizens action, although the exact contours of those measures are not spelled out''), modified, 746 F. Supp. 976 (1990) (holding state and district liable for failing to satisfy SIP commitment).

[121] CARB Resolution 19–26 and Technical Corrections Document.

[122] CARB Resolution 19–26 at para. A.5.

[123] Id. at para. A.6.

[124] The substitute measures or rules would, therefore, be enforceable by the EPA and citizens under the CAA upon approval into the SIP.

[125] See EPA, Memorandum dated November 22, 2011, from Janet McCabe, Deputy Assistant Administrator, EPA Office of Air and Radiation, to Air Division Directors, EPA Regions 1–10, Attachment B (''Guidelines to States Agencies for Preparing the Public Notices for State Implementation Plan (SIP) Revisions'') (noting that state public notices must state that the regulation

If, following an insufficiency finding by the EPA, CARB fails to adopt and submit prohibitory control measures that fully address the identified shortfall in required emission reductions by the relevant deadline, citizens may sue CARB for violating its SIP commitment.

Even if the EPA does not make an insufficiency finding, citizens may independently enforce the tonnage commitments against CARB by reviewing CARB's annual demonstration reports. As explained in Response 5, the Amended Valley Incentive Measure obligates CARB to provide, in each annual demonstration report submitted to the EPA from May 2021 through May 2025, detailed information about each incentive project that CARB is relying on to achieve the necessary emission reductions, including descriptions of both the old (replaced) and new equipment sufficient to independently calculate emission reductions.[126] Each of these annual demonstration reports must be readily available to the public on CARB's website upon submission to the EPA and remain available through December 31, 2030.[127] If CARB's 2024 annual demonstration report (which is due May 15, 2024) fails to demonstrate that the identified projects have achieved 4.83 tpd of NO_X emission reductions and 0.24 tpd of $PM_{2.5}$ emission reductions from the 2024 baseline inventory in the 2018 $PM_{2.5}$ Plan, and CARB has not submitted substitute control measures to address the shortfall, citizens may sue CARB for violating its SIP commitment. Likewise, if CARB's 2025 annual demonstration report (due May 15, 2025) fails to demonstrate that the identified projects have achieved 4.46 tpd of NO_X emission reductions and 0.26 tpd of $PM_{2.5}$ emission reductions from the 2025 baseline inventory in the 2018 $PM_{2.5}$ Plan, and CARB has not submitted substitute control measures to address the shortfall, citizens may sue CARB for violating its SIP commitment. Thus, the tonnage commitments remain enforceable even if the EPA has not made an insufficiency finding in accordance with paragraph A.5 or A.6 of CARB Resolution 19–26. See Response 9.

Comment 8: Earthjustice states that CARB's obligation to ''provide publicly available annual demonstration reports'' is a ''throw away requirement.'' According to Earthjustice, while it might be possible to show that CARB did not provide a report, the contents of the report are so vague that any document would likely pass muster. Earthjustice asserts that although the State must monitor compliance and project whether projects will achieve reductions on time, there are no consequences, for example, if CARB finds noncompliance is rampant or there is no possibility that projects will achieve emission reductions on time.

Response 8: We disagree with Earthjustice's assertion that the annual demonstration reports are ''throw away'' requirements and that ''the contents of the report are so vague that any document would likely pass muster.'' As discussed in Response 4, the Amended Valley Incentive Measure obligates CARB to include the following information in each annual demonstration report that it submits to the EPA by May 15 of each year from 2021 through 2025: (1) Specific information about the projects funded through the previous calendar year that CARB is relying on to fulfill the tonnage commitment; [128] (2) a description of any changes to the applicable guidelines and related impacts on program integrity; (3) a description of CARB's and the District's actions to monitor selected Carl Moyer and FARMER projects for compliance with contract requirements; and (4) a determination of whether the identified projects are projected to fulfill the NO_X and $PM_{2.5}$ tonnage commitments in the San Joaquin Valley by the relevant deadlines.[129] CARB's supporting analysis in the Demonstration further describes the project-specific information for Carl Moyer and FARMER projects that CARB intends to include in each annual demonstration report including, among other things, the project life, post-inspection date,[130] vehicle identification number (VIN), equipment serial number, activity information (*i.e.,* annual hours of operation), percentage of operations occurring in California and in the San Joaquin Valley area, equipment and engine make and model, engine horsepower and tier, vehicle fuel type, and engine emission level (*i.e.,* emission factor).[131]

These provisions ensure that CARB's annual demonstration reports will contain both the project-specific information needed to independently calculate the emission reductions that CARB attributes to each project and the programmatic information needed to determine whether CARB and the District are taking appropriate steps to ensure that the identified projects comply with the applicable program criteria. If CARB's annual demonstration report for a given year fails to provide any of the information described in paragraphs A.3, B.2, or D.2 of CARB Resolution 19–26, as amended by the Technical Corrections Document, the EPA or citizens may bring an enforcement action against CARB for violating its reporting obligations. See Response 4.

We also disagree with Earthjustice's comments about CARB's monitoring obligations in the Valley Incentive Measure and its claim that there are no consequences if CARB finds that noncompliance is rampant or that the identified projects cannot achieve emission reductions on time. As we explained in Response 4, CARB is obligated to monitor the District's implementation of estimated numbers of incentive projects in accordance with specified portions of the relevant program criteria for purposes of determining whether those projects will fulfill specific NO_X and $PM_{2.5}$ tonnage commitments by 2024 and 2025. Additionally, CARB must report annually on the actions that both CARB and the District have taken to monitor Carl Moyer and FARMER projects for compliance with contract requirements. If the EPA determines that information submitted by CARB is insufficient to demonstrate that it will fulfill a particular tonnage commitment on schedule, CARB must adopt and submit substitute measures to the EPA that address any shortfall in emission reductions by specified dates. For example, if the EPA finds, during its review of the annual demonstration reports for 2021 and 2022, that a substantial number of identified projects have not complied with contract terms, or that the total number of projects is insufficient to ensure that CARB will meet its NO_X and $PM_{2.5}$ tonnage commitments by December 31, 2023, the EPA would make an insufficiency finding and thus trigger CARB's

or document at issue will be submitted to the EPA for approval into the SIP).

[126] CARB Resolution 19–26, paras. A3, B.2, C.3, and D.2.

[127] Id. at paras. B.3, C.4., and D.3.

[128] CARB must identify each project that it is relying upon to achieve emission reductions ''by project identification number, project life and implementation date, description of both baseline and new equipment sufficient to independently calculate emision reductions, applicable incentive program guideline, and quantified emission reductions.'' CARB Resolution 19–26, paras. A.3.a.i and A.3.b.i.

[129] Id. at paras. B.2 and D.2.

[130] The ''post-inspection date'' is the date on which the District verifies that the old equipment has been destroyed and that the new equipment has been purchased, is operational, and is the same equipment that was used in the emission reduction calculations. 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 3, Section X (''Project Post-Inspection'').

[131] Demonstration, 24–29 (discussing Carl Moyer project information) and 48–52 (discussing FARMER project information).

obligation to adopt and submit substitute control measures. If, following such an insufficiency finding by the EPA, CARB fails to adopt and submit substitute control measures that fully address the identified shortfall in required emission reductions by the relevant deadline, both the EPA and citizens may sue CARB for violating its SIP commitment. See Response 2. Any insufficiency finding that the EPA makes would be available to the public upon request and available on the EPA's website at *https://www.epa.gov/sips-ca*.

Even if the EPA does not make an insufficiency finding, citizens may verify whether CARB has met the tonnage commitment by independently reviewing CARB's annual demonstration reports, and thereby enforce the tonnage commitment directly. As explained in Response 5, the Amended Valley Incentive Measure obligates CARB to provide detailed information in each annual demonstration report and to make each of these reports readily available to the public on CARB's website or available upon request. If CARB's 2024 annual demonstration report (which is due May 15, 2024) fails to demonstrate that the identified projects have achieved 4.83 tpd of NO_X emission reductions and 0.24 tpd of $PM_{2.5}$ emission reductions from the 2024 baseline inventory in the 2018 $PM_{2.5}$ Plan, and CARB has not submitted substitute control measures to address the shortfall, citizens may sue CARB for violating its SIP commitment. For example, if citizens find, upon review of the 2024 annual demonstration report and related project documents, that emission reductions have not occurred because a substantial number of identified projects have not complied with contract terms, or that the total number of projects is insufficient to meet CARB's NO_X and $PM_{2.5}$ tonnage commitments by December 31, 2023, citizens may sue CARB for violating its SIP commitment. See Response 5.

All Carl Moyer and FARMER projects are subject to detailed contract provisions that must, among other things, specify the repercussions for noncompliance with contract requirements.[132] Under the 2011 and 2017 Carl Moyer Guidelines, each project contract must include: (1) The name and contact information of the grantee; (2) specified timeframes for ''project completion'' (the date the project ''post-inspection'' confirms that the project has become operational) and ''project implementation'' (the project life used in the project cost-effectiveness calculation); (3) detailed information on both baseline and new equipment, including documentation adequate to establish historical annual usage; (4) requirements for the grantee to maintain the equipment according to the manufacturer's specifications for the life of the project; (5) annual reporting requirements; (6) a provision authorizing the District, CARB, and their designees to conduct fiscal audits and to inspect the equipment and associated records during the contract term; (7) requirements to maintain and retain project records for at least three years after contract expiration; (8) repercussions for noncompliance; and (9) a statement that CARB is authorized to enforce the terms of the contract at any time during the contract term to ensure that emission reductions are obtained.[133] These project contracts, in addition to other project-specific records, will be available to the public upon request beginning May 15, 2021, and through 2029,[134] thereby enabling the public to verify the project-specific information provided in CARB's annual demonstration reports.

Additionally, both CARB and the District are authorized to ''seek any remedies available under the law for noncompliance with Carl Moyer program requirements and nonperformance with the contract,'' including cancelling the contract and recapturing program funds.[135] Should CARB determine that the District's oversight and enforcement of the program is insufficient, CARB may also recapture funds granted to the District that have not yet been awarded to approved projects.[136]

These provisions of the 2011 and 2017 Carl Moyer Guidelines, together with CARB's commitments in the Amended Valley Incentive Measure, enable the EPA and the public to independently verify the emission reductions attributed to each incentive project that CARB has identified in its annual demonstration reports to demonstrate compliance with the tonnage commitment. For all of these reasons, we disagree with Earthjustice's claim that CARB's reporting obligations in the Valley Incentive Measure are insufficient to ensure that emission reductions will occur in a timely manner.

Comment 9: Earthjustice asserts that the absence of defined violations makes independent verification impossible, and that although CARB says it is ''monitoring'' implementation, neither the EPA nor citizens can independently verify or prove otherwise. Earthjustice claims that an even more fundamental problem around verification is that the emission reductions to be achieved, in theory, will come from projects under the Carl Moyer and FARMER programs that neither the EPA nor citizens can independently verify, and from the NRCS program that no one other than NRCS can verify. Earthjustice states that measures that preclude verification and enforcement by the EPA and citizens do not meet the enforceability requirements of the Act.

Response 9: We disagree with Earthjustice's claim that neither the EPA nor citizens can independently verify whether CARB is monitoring implementation of the identified incentive projects. CARB's commitment to monitor District implementation of projects in accordance with the 2011 and 2017 Carl Moyer Guidelines is enforceable through specific reporting provisions in the Amended Valley Incentive Measure that require CARB to report annually on, among other things, the incentive projects it is relying on to achieve emission reductions and the actions that CARB and the District have taken to ensure that these projects comply with the contracts issued in accordance with the applicable Carl Moyer Guidelines. See Response 2 and Response 4.

[132] Cal. Health & Safety Code section 44288(d) (''Funds shall be awarded in conjunction with the execution of a contract that obligates the state board or a participating district to make the grant and obligates the grantee to take the actions described in the grant application''), 2011 Carl Moyer Guidelines, Part 1, Chapter 3, Section Y (''Minimum Contract Requirements''), para. 11 and 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 3, Section V (''Minimum Contract Requirements''), para. 11.

[133] 2011 Carl Moyer Guidelines, Part 1, Chapter 3, Section Y (''Minimum Contract Requirements'') and Chapter 9, Section C (''Project Criteria''), para. 2.E (requiring documentation showing ownership by the grantee for the previous 24 months), 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 3, Section V (''Minimum Contract Requirements'') and Chapter 5, Section D (''Project Criteria''), para. 4(E)(1) (requiring documentation showing ownership by the grantee for the previous 24 months).

[134] CARB Resolution 19–26, paras. B.5 and D.5 (added by Technical Corrections Document, paras. 7 and 11) (requiring that CARB provide to any requestor ''all documents relied upon in the preparation of any annual demonstration report and available in the relevant project file, including: project applications, grant contracts, inspection-related documents (including photographic documentation of baseline engine destruction), and any available audit-related documentation and annual grantee reports'').

[135] 2011 Carl Moyer Guidelines, Part 1, Chapter 3, Section Y (''Minimum Contract Requirements''), para. 11 and 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 3, Section V (''Minimum Contract Requirements''), para. 11.

[136] 2011 Carl Moyer Guidelines, Part 1, Chapter 3, Section T (''Program Non-Performance''), para. 4. and 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 3, Section Q (''Program Nonperformance''), para. 3.

We also disagree with Earthjustice's assertion that projects relied on in the Valley Incentive Measure cannot be independently verified by the EPA or the public. As explained in Response 4 and Response 8, the Amended Valley Incentive Measure obligates CARB to provide, in each annual demonstration report, detailed information about each incentive project funded through the previous year that CARB is relying on to achieve the required NO_X and $PM_{2.5}$ emission reductions, including descriptions of both baseline and new equipment sufficient to independently calculate emission reductions.[137] Consistent with these obligations, CARB has submitted an Excel spreadsheet populated with detailed project-specific information for both baseline and new equipment sufficient to independently calculate emission reductions for all Carl Moyer and FARMER projects completed as of July 26, 2019, which we refer to as ''Detailed Spreadsheet HJ.'' [138] We explain below how the emission reductions for each project may be independently verified, based on the project data provided in Detailed Spreadsheet HJ and the quantification methodologies provided in the 2011 and 2017 Carl Moyer Guidelines.

For Carl Moyer and FARMER projects, the accuracy of the project data provided in each annual demonstration report may be verified through independent review of specific documents that grantees and the District must maintain in accordance with the Carl Moyer Guidelines, all of which will be available for public review in accordance with paragraphs B.5 and D.5 of CARB Resolution 19–26.[139] First, actions required of grantees under the 2011 and 2017 Carl Moyer Guidelines are independently verifiable through (1) pre-project and post-project on-site inspections (with photographic documentation) that the District and/or CARB must carry out pursuant to the applicable guidelines, and (2) documents that each grantee is required to maintain and/or submit to the District in accordance with detailed contract provisions.

For example, the 2017 Carl Moyer Guidelines require, among other things, that (1) all project applications include documentation of existing engine usage in previous years (*e.g.,* miles traveled, hours operated, or fuel consumed per year); (2) that the District conduct a ''pre-inspection'' of each application deemed eligible for funding, to verify information regarding the baseline equipment; (3) that the District conduct a ''post-inspection'' of each funded project to verify destruction of the baseline engine through photographic or video evidence, and record, among other things, information regarding the new equipment as needed to provide a basis for emission calculations and to ensure contract enforceability; and (4) that the District's project files include all required ''pre-inspection'' and ''post-inspection'' documentation, including photographic documentation of the engine, vehicle, or equipment information (*e.g.,* a legible serial number and/or other identifying markings) and photographic evidence of the scrapped or destroyed engine.[140]

Second, the 2017 Carl Moyer Guidelines specifically define the required elements of each contract and the types of actions that constitute violations of such contracts. Specifically, each project contract must include: (1) The name and contact information of the grantee; (2) specified timeframes for ''project completion'' and ''project implementation''; (3) detailed information on baseline and new equipment, including documentation adequate to establish historical annual usage; (4) requirements for equipment maintenance; (5) annual reporting requirements; (6) authorization for the District, CARB, and their designees to conduct fiscal audits and equipment and associated records inspection; (7) requirements to retain project records after contract expiration; and (8) repercussions for contract noncompliance, including cancellation of the contract and recapture of program funds.[141] See Response 8.

Third, the 2017 Carl Moyer Guidelines require that all grantees submit specific types of project records to the District and also require the District to maintain such records for specified periods of time. Specifically, each contract executed by the District must require the grantee to maintain project records for at least three years after contract expiration, and to submit annual or biennial reports to the District. Additionally, the District must keep each ''project file'' for a minimum of three years after the end of the contract term. A ''project file'' generally includes a copy of the application, the contract, a completed pre- and post-inspection form, photographs of the destroyed engine, and the annual reports submitted by the grantee.[142]

These requirements of the 2017 Carl Moyer Guidelines, which are substantively identical to similar provisions in the 2011 Carl Moyer Guidelines, ensure that the District will maintain project-specific documents sufficient for the EPA and the public to verify the accuracy of CARB's emission reduction calculations for the Carl Moyer and FARMER projects listed in each annual demonstration report. Specifically, the EPA and the public may verify CARB's emission reduction calculations not only by independently calculating project-specific emission

[137] CARB Resolution 19–26, para. A.3.

[138] CARB, ''Carl Moyer/FARMER Emissions Reductions Calculator'' (''Detailed Spreadsheet HJ''), available as ''Appendices H and J—Detailed'' at *https://ww2.arb.ca.gov/resources/documents/implementation-state-sip-strategy* (last visited November 16, 2021). This spreadsheet is also available as ''ag_appx_h_j_detailed_021120.xlsx'' at *www.regulations.gov* under docket number EPA–R09–OAR–2020–0079. We understand that CARB will include, in each annual demonstration report submitted to the EPA beginning May 15, 2021, similar spreadsheets providing detailed information about each project that CARB relies on to fulfill its tonnage commitments in the Amended Valley Incentive Measure. The EPA is currently reviewing the first annual demonstration report that CARB submitted to EPA on May 14, 2021, including the associated project spreadsheets. This report is available at *https://ww2.arb.ca.gov/resources/documents/implementation-state-sip-strategy* and available as ''2021 Annual Demonstration Report'' at *www.regulations.gov* under docket number EPA–R09–OAR–2020–0079.

[139] Paragraphs B.5 and D.5 of CARB Resolution 19–26 (added by paragraphs 7 and 11 of the Technical Corrections Document) obligate CARB to provide to the public upon request, for Carl Moyer and FARMER projects, beginning 15, 2021 and through 2029: ''all documents relied upon in the preparation of any annual demonstration report and available in the relevant project file, including: project applications, grant contracts, inspection-related documents (including photographic documentation of baseline engine destruction), and any available audit-related documentation and annual grantee reports.''

[140] 2017 Carl Moyer Program Guidelines, Volume I, Part 1, Chapter 3, Section T (''Application Evaluation and Project Selection''), para. 3, Section W (''Project Pre-Inspection''), and Section X (''Project Post-Inspection''). See also 2011 Carl Moyer Program Guidelines, Part 1, Chapter 3, Section W (''Application Evaluation and Project Selection''), para. 3, Section Z (''Project Pre-Inspection''), and Section AA (''Project Post-Inspection'').

[141] 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 3, Section V (''Minimum Contract Requirements'') and Chapter 5, Section D (''Project Criteria''), para. 4(E)(1) (requiring documentation showing ownership by the applicant for the previous 24 months). See also 2011 Carl Moyer Guidelines, Part 1, Chapter 3, Section Y (''Minimum Contract Requirements'') and Chapter 9, Section C (''Project Criteria''), para. 2(E) (requiring documentation showing ownership by the grantee for the previous 24 months).

[142] 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 3, Section T (''Application Evaluation and Project Selection), para. 1, Section V (''Minimum Contract Requirements''), para. 1, Section W (''Project Pre-Inspection''), para. 4, Section X (''Project Post-Inspection''), para. 1, and Section Z (''Grantee Annual Reporting''), para. 3. See also 2011 Carl Moyer Guidelines, Part 1, Chapter 3, Section W (''Application Evaluation and Project Selection''), para. 1, Section Y (''Minimum Contract Requirements''), para. 1, Section Z (''Project Pre-Inspection''), para. 4, Section AA (''Project Post-Inspection''), para. 1, and Section CC (''Grantee Annual Reporting''), para. 3.

reductions using the quantification methodologies provided in the 2017 Carl Moyer Guidelines and the project data provided in the annual demonstration report, but also by confirming the accuracy of the project data provided in CARB's annual demonstration reports, through independent review of the project-specific documents that the District must maintain under the 2011 and 2017 Carl Moyer Guidelines (*e.g.,* the project contract and associated pre-inspection and post-inspection documentation). All of these project-specific documents will be available for public review in accordance with paragraphs B.5 and D.5 of CARB Resolution 19–26.[143] Accordingly, the EPA and citizens can obtain the information necessary to quantify and verify the emission reductions that CARB attributes to Carl Moyer and FARMER projects to fulfill the tonnage commitments in the Amended Valley Incentive Measure.

To demonstrate how the public can quantify and verify the emission reductions identified in each annual demonstration report, we randomly selected three of the projects listed in Appendix H and Appendix J of the Demonstration [144] and independently calculated the emission reductions for these projects based on the data inputs provided in Detailed Spreadsheet HJ and the relevant quantification methodologies in the 2011 and 2017 Carl Moyer Guidelines. The projects that we randomly selected from Appendix H and Appendix J of the Demonstration are identified in Table 1.

TABLE 1—CARL MOYER AND FARMER PROJECTS, AND SELECTED PROJECT INFORMATION, FROM DETAILED SPREADSHEET HJ (SEE ALSO DEMONSTRATION, APPENDIX H AND APPENDIX J)

Equipment identifier	Function vocation	Applicable program guideline	Post-Inspection date	Baseline engine model year	NO_X reductions (tons per day)	$PM_{2.5}$ reductions (tons per day)
C–60539–1–A1	Agricultural tractor replacement.	2018 FARMER (2017 Carl Moyer Guidelines).	7/15/2019	2005	0.000643	0.0000297
C–49610–1A	Agricultural tractor replacement.	2017 Carl Moyer Guidelines.	1/23/19	1992	0.000747	0.0000625
C–27026–1A	Agricultural tractor replacement.	2011 Carl Moyer Guidelines.	10/26/15	1996	0.00217	0.0000724

We independently calculated the emission reductions for the selected projects using the data inputs included in Detailed Spreadsheet HJ and provided our analysis in a memorandum to file dated February 27, 2021, which we refer to as the ''EPA Calculation Memo.'' [145] Our calculations replicated the emission reductions as reported by CARB for all three projects.

Although we calculated emission reductions for only three randomly selected projects from Appendix H and Appendix J, the availability of the project information in Excel format allows for the verification of emission reductions from all projects relied on in the Amended Valley Incentive Measure in a fraction of the time it would take to perform manual calculations. Use of Excel to perform these emission reduction calculations becomes especially advantageous (in lieu of manual calculation) as the number of implemented projects increases each year. The EPA Calculation Memo provides more information on how to use Excel to calculate emission reductions from these projects.[146]

Additionally, at our request, CARB submitted project-specific documents, including the project application, baseline engine usage records, grant contract, documentation of destruction, and pre- and post-inspection photographs, for two of the projects listed in Table 1 (Carl Moyer project number C–27026–1A and FARMER project number C–60539–1–A1).[147] We reviewed the information contained in these project records and confirmed that it is generally consistent with the information provided in Detailed Spreadsheet HJ for these two projects.[148]

In sum, the EPA and the public can verify the emission reductions that CARB has attributed to each Carl Moyer and FARMER project it is relying on to achieve the NO_X and $PM_{2.5}$ tonnage commitment in the Amended Valley Incentive Measure by doing the following: (1) For each project identified in an annual demonstration report (or for a random selection of such projects), reviewing the project-specific documents that CARB must provide upon request, to verify the accuracy of the project data provided in CARB's annual demonstration report, and (2) independently calculating the emission reductions for each project identified in the annual demonstration report (or for a random selection of such projects), based on the relevant project data (*e.g.,* annual hours of operation, baseline and new engine model year, engine tier, horsepower, and project life) and the applicable quantification methodologies in the 2011 and 2017 Carl Moyer Guidelines. Thus, CARB's commitments concerning the annual demonstration reports and related project documents, together with detailed inspection, recordkeeping and reporting requirements in the 2011 and 2017 Carl Moyer Guidelines, enable the EPA and the public to verify the emission reductions achieved by each project that CARB is relying on to fulfill its tonnage commitment in the Amended Valley Incentive Measure.

Comment 10: Earthjustice asserts that the goal of the rule is to remove the

[143] Technical Corrections Document, paras. 7 and 11.

[144] Demonstration, Appendix H (''San Joaquin Valley Agricultural Equipment Incentive Measure, Carl Moyer Project List''), Appendix J (''San Joaquin Valley Agricultural Equipment Incentive Measure, FARMER Project List''), and Detailed Spreadsheet HJ, available at *https://ww2.arb.ca.gov/resources/documents/implementation-state-sip-strategy,* link entitled ''Appendices H and J—Detailed'' (last visited November 16, 2021) (also available as ''ag_appx_h_j_detailed_021120.xlsx'' at *www.regulations.gov* under docket number EPA–R09–OAR–2020–0079).

[145] EPA, Memorandum dated February 27, 2021, from Rebecca Newhouse, EPA Region IX, to File, Subject: ''Sample emission reduction calculations for selected Carl Moyer and FARMER off-road, heavy, mobile, diesel agricultural equipment replacement projects'' (hereafter ''EPA Calculation Memo'').

[146] Id.

[147] Email dated March 11, 2021, from Austin Hicks, CARB, to Rynda Kay, EPA Region IX, Subject: RE: Requesting project documentation for Valley Incentive Measure projects; 1 of 2 C–27026–1–1A and email dated March 11, 2021, from Austin Hicks, CARB, to Rynda Kay, EPA Region IX, Subject: RE: Requesting project documentation for Valley Incentive Measure projects; 2 of 2 C–60539–1–1A.

[148] EPA, Memorandum dated April 26, 2021, from Rynda Kay, EPA Region IX, to File, Subject: ''Review of CARB project documentation.''

requirement for enforceability against the actual sources by making CARB responsible for the emission reductions. According to Earthjustice, the EPA appears to admit that the actual emissions reductions achieved through these various incentives do not satisfy the Act's criteria for enforceability but claim that the defect can be ''cured by inventing an umbrella commitment for CARB to fill any shortfall.'' Earthjustice claims that the ''commitment to make up the difference, however, does not in fact cure the unenforceability of the reductions credit[ed] toward that commitment,'' and that the emission reductions that CARB commits to achieve are measured only by CARB and the District (and NRCS), and cannot be verified by anyone else. Earthjustice states that if CARB claims that it has satisfied its 5.9 tpd commitment because the incentive programs worked, there is no way for the EPA or others to confirm that this is true. Earthjustice states that the EPA and citizens cannot compel the grant recipients to support the data submitted to CARB, the District, or NRCS, and that the EPA and citizens must trust that these agencies have done their due diligence in verifying the data themselves—a task that Earthjustice claims is not really in the interest of these agencies because they do not want to be on the hook for making up any shortfall. Likewise, according to Earthjustice, if CARB claims that its substitute measures reduce emissions by whatever the shortfall, there is nothing in the rule that ensures anyone else could verify that claim.

Response 10: We disagree with the commenter's assertion that the emission reductions committed to by CARB cannot be verified by anyone other than CARB and the District. As explained in Response 2 and Response 4, CARB has committed to submit annual demonstration reports containing detailed project data that enables the public and the EPA to independently calculate the emission reductions from each identified project. Additionally, the 2011 and 2017 Carl Moyer Guidelines [149] require that grantees submit, and that the District maintain, project documents sufficient for the EPA and the public to verify the accuracy of the project data provided in CARB's annual demonstration reports (*e.g.,* the project contract and associated pre-inspection and post-inspection documentation). See Response 9.

Although we agree with the commenter that neither the EPA nor the public can compel grantees to provide additional data or documentation, the 2011 and 2017 Carl Moyer Guidelines include a number of requirements to ensure that project-specific information is supported by the grantee with additional documentation, and that equipment-specific information supplied by the grantee is verified by the implementing agency (in this case, the SJVUAPCD). For example, the 2017 Carl Moyer Guidelines require that old equipment be inspected by the implementing agency with corresponding written and photographic documentation, confirming (1) that the equipment is in usable condition, and (2) that the equipment-specific information provided by the grantee such as the make, model, horsepower, and usage meter reading (referred to as a ''pre-inspection'') is correct.[150] The 2017 Carl Moyer Guidelines also require that new equipment be inspected after purchase and contract execution to confirm the equipment's make, model, horsepower, and usage meter reading, with corresponding written and photographic documentation (referred to as a ''post-inspection'').[151] District staff or an approved salvage yard must take photographs of the destroyed engine and, if a salvage yard verifies engine destruction, the salvage yard must provide that documentation to the air district within ten business days of dismantling the equipment.[152] The implementing agency must include these photographs in the project file.[153] Additionally, the 2017 Carl Moyer Guidelines require grantees to submit documentation that establishes historical annual usage of the old equipment and confirms ownership for the past two years.[154] Contract provisions require grantees to submit annual reports that include annual usage, and time operated in California, for the new equipment until contract expiration.[155] As explained in Response 9, the public has access to all underlying documentation for each Carl Moyer project in accordance with paragraphs B.5 and D.5 of CARB Resolution 19–26.[156] We therefore disagree with Earthjustice's claim that the EPA and the public must ''trust that these agencies have done their due diligence in verifying the data themselves.''

We also disagree with the commenter's assertion that there is no way to verify the emission reductions achieved by the substitute measures that CARB must adopt if the EPA projects an emission reduction shortfall. Specifically, as explained in Response 2 and Response 5, if the EPA determines by August 1, 2022, that information submitted by CARB is insufficient to demonstrate that the emission reductions necessary to fulfill the 2024 tonnage commitments will occur on schedule, CARB must adopt and submit to the EPA, no later than September 1, 2023, substitute measures or rules that will achieve emission reductions addressing the shortfall as expeditiously as practicable and no later than January 1, 2024.[157] Likewise, if the EPA determines by August 1, 2023, that information submitted by CARB is insufficient to demonstrate that the emission reductions necessary to fulfill the 2025 tonnage commitments will occur on schedule, CARB must adopt and submit to the EPA, no later than September 1, 2024, substitute measures or rules that will achieve emission reductions addressing the shortfall as expeditiously as practicable and no later than January 1, 2025.[158] Any such substitute control measure must be adopted following state rulemaking procedures through which the EPA and the public may track the State's progress in achieving the requisite emissions reductions and comment on the State's emission reduction analyses. We expect CARB to make clear during any such rulemaking that it is proposing the identified measure or rule for purposes of submission to the EPA consistent with its commitment in the Amended Valley Incentive Measure.[159] If,

[149] All FARMER projects that CARB relies on to comply with the Amended Valley Incentive Measure are subject to the 2017 Carl Moyer Guidelines, future approved guidelines, and current and future program advisories and mail-outs, except as modified by CARB. Demonstration, 43–45 and 2018 FARMER Guidelines, 17–18; see also TSD, 16–17.

[150] 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 3, Section W (''Project Pre-Inspection'').

[151] Id. at Section X (''Project Post-Inspection'').

[152] 2017 Carl Moyer Guidelines, Volume I, Part 1, Chapter 5, Section D (''Project Criteria'').

[153] Id. at Chapter 3, Section X (''Project Post-Inspection''), para. 1.

[154] Id. at Section V (''Minimum Contract Requirements'') and Chapter 5, Section D (''Project Criteria'').

[155] Id. at Section Z (''Grantee Annual Reporting''), paras. 1 and 2.

[156] Technical Corrections Document, paras. 7 and 11 (requiring that CARB provide to any requestor ''all documents relied upon in the preparation of any annual demonstration report and available in the relevant project file, including: Project applications, grant contracts, inspection-related documents (including photographic documentation of baseline engine destruction), and any available audit-related documentation and annual grantee reports'').

[157] CARB Resolution 19–26, para. A.5.

[158] Id. at para. A.6.

[159] See EPA, Memorandum dated November 22, 2011, from Janet McCabe, Deputy Assistant Administrator, EPA Office of Air and Radiation, to Air Division Directors, EPA Regions 1–10, Attachment B (''Guidelines to States Agencies for

Continued

following an insufficiency finding by the EPA, CARB fails to adopt and submit prohibitory control measures that fully address the identified shortfall in required emission reductions by the relevant deadline, citizens may sue CARB for violating its SIP commitment.

Comment 11: Earthjustice asserts that the EPA's approach ''separates the emission reduction obligation from the emitter and makes the (theoretically) liable party in charge of determining compliance.'' Earthjustice claims that neither the EPA nor citizens can independently verify compliance with the emission reduction commitment and that CARB is given the ability to deem itself in compliance with no possibility for others to challenge that determination.

Response 11: For the reasons provided in Response 2 through Response 10, we disagree with these claims.

Comment 12: Earthjustice states that the absence of defined violations is most apparent when trying to describe what penalties could be assessed or what corrective action could be compelled by a court. For example, Earthjustice asks, if CARB were found in violation of the 5.9 tpd commitment, would CARB be subject to daily penalties under CAA section 113 until it achieved that reduction, or could it be compelled to adopt some replacement measure by the court? Earthjustice also asks how such a suit in equity would be handled under the Eleventh Amendment to the Constitution; whether the commitment to rectify the shortfalls upon an EPA determination negates any such court intervention; and whether the EPA is the arbiter of whether the substitute measures are adequate. If so, Earthjustice asserts, there is effectively no penalty for violating the 5.9 tpd commitment, and the only recourse is to repeatedly challenge the EPA for arbitrarily letting CARB and the District fail to clean the air, which is not subject to remedies under CAA section 113. Earthjustice further asks what the penalty is for failing to monitor implementation or for inadequate reporting, and how a court would determine days of violations. According to Earthjustice, these are not practicably enforceable commitments because the violations are not actually defined. Earthjustice claims that the EPA cannot explain exactly how a violation of these various commitments could be proven and enforced, and what the judicial remedy would be for citizens bringing an enforcement action. According to Earthjustice, this is why no one has ever been able to enforce similar state emission reduction commitments in the past.

Response 12: We disagree with Earthjustice's claim that ''there is effectively no penalty for violating the 5.9 tpd commitment'' and that the only recourse for such a violation is for the public to ''repeatedly challenge the EPA for arbitrarily letting CARB and the District fail to clean the air, which is not subject to remedies under CAA section 113.'' As explained in Response 2 and Response 5, CARB's commitments constitute a specific enforceable strategy for achieving specific amounts of NO_X and $PM_{2.5}$ emission reductions on a fixed schedule and, upon approval into the SIP, become requirements of an ''applicable implementation plan'' as defined in CAA section 302(q). Accordingly, these commitments are enforceable by citizens under CAA section 304(a)(1) and by the EPA under CAA section 113(a)(1). CARB has also clearly expressed its decision to voluntarily commit itself to fulfilling the tonnage commitment and to being held accountable for failure to fulfill this commitment.[160]

The EPA has approved enforceable SIP commitments in the past and courts have enforced these commitments against states that failed to comply with them.[161] As the Second Circuit has stated, ''a plan, once adopted by a state and approved by the EPA, becomes controlling and must be carried out by the state,'' and the U.S. district courts are ''obligated, upon a showing that the state has violated the plan, to issue appropriate orders for its enforcement.'' [162]

Several district courts have, in response to citizen suits brought under CAA section 304(a), issued orders to enforce SIP-approved commitments by states to adopt and implement specific types of control measures. In *American Lung Ass'n of N.J.* v. *Kean,* 670 F. Supp. 1285 (D.N.J. 1987), aff'd, 871 F.2d 319 (3rd Cir. 1989), the court found New Jersey liable for failure to comply with SIP-approved commitments to implement seven specific ozone-control strategies identified in the submitted plan. Rejecting New Jersey's argument that its SIP compelled it only to study the feasibility of the seven strategies and to implement only those strategies that it found feasible, the court concluded that the text of the SIP ''manifests an intention on the part of New Jersey to commit itself to the schedule'' that plaintiffs alleged New Jersey had violated—*i.e.,* a schedule for proposing regulations, promulgating final regulations, and implementing those final regulations through proper enforcement.[163] The court granted plaintiff's motion for partial summary judgment on the issue of New Jersey's liability under the CAA for failure to comply with its SIP and ordered the parties to submit proposed timetables for New Jersey's compliance with its SIP. In the second phase of trial, the court adopted New Jersey's proposed schedule for promulgation and implementation of regulations, which had been approved by the EPA and plaintiffs.[164] On appeal brought by petroleum industry trade associations, the Court of Appeals for the Third Circuit affirmed the district court's order.[165]

In *Natural Resources Defense Council, Inc.* v. *N.Y. State Dept. of Env. Cons.,* 668 F. Supp. 848 (S.D.N.Y. 1987), the court held that New York had violated its SIP-approved commitments to study and implement specific strategies for reducing volatile organic compound (VOC) emissions from four major source categories. Rejecting New York's arguments that summary judgment on liability would be inappropriate because of its reasonable efforts to implement the SIP, unavoidable technical difficulties, and the failure of other state and federal environmental agencies that share implementation responsibilities to take timely action, the court found that ''[t]he very fact that the New York SIP has been violated mandates a finding of liability, regardless of the reasons for the violation.'' [166] The court granted plaintiff's motion for partial summary

Preparing the Public Notices for State Implementation Plan (SIP) Revisions'') (noting that state public notices must state that the regulation or document at issue will be submitted to the EPA for approval into the SIP).

[160] Demonstration, 29 and 52 (stating that ''CARB is the responsible party for enforcement of this measure and is responsible for achieving the emission reductions from this measure'').

[161] See, *e.g., American Lung Ass'n of N.J.* v. *Kean*, 670 F. Supp. 1285 (D.N.J. 1987), aff'd, 871 F.2d 319 (3rd Cir. 1989); *NRDC, Inc.* v. *N.Y. State Dept. of Env. Cons.*, 668 F. Supp. 848 (S.D.N.Y. 1987); *Citizens for a Better Env't* v. *Deukmejian*, 731 F. Supp. 1448, recon. granted in par, 746 F. Supp. 976 (N.D. Cal. 1990); *Coalition for Clean Air* v. *South Coast Air Quality Mgt. Dist.*, No. CV 97–6916–HLH (C.D. Cal. Aug. 27, 1999). Further, if a state fails to fulfill its commitments, the EPA may make a finding of failure to implement the SIP under CAA section 179(a), which starts an 18-month period for the state to correct the non-implementation before mandatory sanctions apply.

[162] *Friends of the Earth* v. *Carey,* 535 F.2d 165, 169, 173 (2d Cir. 1976). *See also Natural Resources Defense Council* v. *N.Y. Department of Environmental Conservation,* 668 F. Supp. 848, 852 (S.D.N.Y.1987).

[163] 670 F. Supp. 1285, 1290.

[164] 871 F. 2d 319.

[165] Id. at 327 (noting that the ''scheduling order entered by the district court is an equitable order, made within the ambit of the district court's discretion to fashion appropriate remedies'').

[166] 668 F. Supp. 848, 852.

judgment on the issue of New York's liability under the CAA for failure to comply with its SIP and, following the parties' submissions of proposed implementation schedules, issued a detailed scheduling order including specific deadlines for New York to complete studies, propose and adopt regulations, and require full compliance with the adopted regulations for each of the four VOC source categories.[167]

In *Coalition for Clean Air* v. *South Coast Air Quality Mgt. Dist.,* No. CV 97–6916–HLH (C.D. Cal. Aug. 27, 1999), the court held that the South Coast Air Quality Management District (SCAQMD) had violated its SIP-approved commitments by failing to adopt and implement 31 of 32 control measures identified in its ozone SIP. The SCAQMD provided numerous reasons for its failure to adopt and implement these measures, including its review of updated emission inventories showing that the emission of some source categories were drastically lower than the SIP had assumed, the unavailability of technologies that the SCAQMD had previously assumed would be developed, and the excessive costs of certain measures compared with the pollution to be reduced. The court rejected these arguments, finding that ''[o]nce liability is established, the District Court is required by the Act to issue an injunction to compel compliance with the SIP'' and that ''[m]istakes or failures in factual assumptions must be considered by the EPA, not by the Court, whose duty it is to enforce the SIP as written.'' [168] The court issued an injunction establishing specific deadlines for the SCAQMD to adopt and implement the 31 control measures.

Thus, if a district court found CARB in violation of the 4.83 tpd NO_X emission reduction commitment for 2024, the holdings in the cases cited above suggest that a district court would be required to issue appropriate orders for its enforcement, such as an order compelling CARB to adopt one or more enforceable measures that achieve 4.83 tpd of NO_X emission reductions by a date certain. Upon CARB's adoption and submission of any such substitute measures, the EPA would determine, through notice-and-comment rulemaking, whether the measure is sufficient to achieve the necessary emission reductions.

Earthjustice asks the EPA to explain how a suit in equity would be handled under the Eleventh Amendment to the Constitution but fails to articulate a basis for finding the commitments in the Valley Incentive Measure problematic or difficult to enforce on constitutional grounds. Although the Eleventh Amendment generally grants immunity to states from suit for money damages or equitable relief without their consent, it does not grant states immunity from suit for injunctive relief (*i.e.,* to prevent future violations of federally-mandated SIP requirements) where the state itself has submitted SIP commitments and thereby consented to enforcement in federal court. As stated in *NRDC,* the district courts have authority under the CAA to enforce SIP provisions, and ''[i]t cannot be argued'' that ''an order implementing [a SIP control strategy] as promptly as possible would impinge on an area of state sovereignty.'' [169] Similarly, in *Friends of the Earth* v. *Carey,* the Second Circuit rejected New York City's claims of state sovereign immunity from suit in federal court and found that the City's decision ''voluntarily to commit itself to enforcement of the Plan'' constituted a waiver of such immunity.[170] The court noted that, in the context of a citizen suit to enforce the provisions of the SIP, ''the choices and procedures are the products of State choice, not of federal policy, and may legitimately be enforced by the district court.'' [171]

Comment 13: Earthjustice states that the EPA's proposed approach creates a new type of ''black box'' for national ambient air quality standards (NAAQS) other than ozone and without the conditions required under CAA section 182(e)(5). Earthjustice asserts that, ''[l]ike the black box, CARB and the District are now allowed to promise to reduce emissions without actually making any enforceable commitment as to how,'' but that ''unlike the black box, which at least requires actual contingency measures to be adopted and in place years before the compliance date, there are no actual backstops in place to make up for a shortfall.'' Earthjustice asserts that the EPA must explain why Congress would have allowed such an approach after clearly providing only limited flexibility in section 182(e)(5), and only allowing such flexibility for long-term plans related to ozone.

Response 13: We disagree with Earthjustice's suggestion that our proposed approach to approving the Valley Incentive Measure (or portions thereof) for SIP credit ''creates a new type of 'black box' '' that is inconsistent with congressional intent. Section 182(e)(5) of the CAA allows the EPA to approve plan provisions that ''anticipate development of new control techniques or improvement of existing control technologies''—*i.e.,* control measures yet to be defined—for ozone nonattainment areas classified as ''extreme'' under subpart 2 of part D, title I of the Act. This provision is often referred to as the ''black box'' or ''new technology'' provision of the Act.

Unlike the new technology provisions that the EPA has approved in attainment plans for extreme ozone nonattainment areas,[172] the Amended Valley Incentive Measure is not a provision that anticipates the development, adoption, and implementation of control measures yet to be defined. As explained in Response 2 and Response 4, CARB's commitments in the Amended Valley Incentive Measure constitute a specific enforceable strategy for achieving specific amounts of NO_X and $PM_{2.5}$ emission reductions in the San Joaquin Valley, either through implementation of agricultural equipment replacement projects subject to specific portions of the 2011 or 2017 Carl Moyer Guidelines or through substitute measures adopted and submitted in accordance with specified deadlines.[173] The measure obligates CARB to monitor and report annually on the implementation of estimated numbers of such incentive projects and to adopt and submit substitute control measures on a fixed schedule, if the EPA determines that information submitted by CARB in the annual demonstration reports is insufficient to demonstrate that the identified incentive projects will fulfill the tonnage commitment.[174]

For these reasons, we also disagree with Earthjustice's claim that the Valley Incentive Measure allows CARB and the District ''to promise to reduce emissions without actually making any enforceable commitment as to how'' and without providing for any ''backstops'' to make up for a shortfall in required emission reductions. See Response 2 and Response 4.

[167] Id. at 858 ff.

[168] Case No. CV97–6916–HLH (C.D. Ca., August 27, 1999) at 3, 4 (citing CAA section 304(a) and *Friends of the Earth,* 535 F.2d 165 (2d Cir.1976)).

[169] 668 F.Supp. 848, 854 (citing *Friends of the Earth* v. *Carey,* 552 F.2d 25, 39 (2d Cir. 1977)).

[170] *Friends of the Earth* v. *Carey,* 552 F.2d 25, 35 (2d Cir.), *cert. denied sub nom. Beame* v. *Friends of the Earth,* 434 U.S. 902, 98 S.Ct. 296, 54 L.Ed.2d 188 (1977).

[171] 552 F.2d at 39.

[172] See, *e.g.,* 77 FR 12652 (March 1, 2012) (approving San Joaquin Valley attainment plan for 1997 8-hour ozone NAAQS), 77 FR 12674 (March 1, 2012) (approving South Coast attainment plan for 1997 8-hour ozone NAAQS), and 84 FR 52005 (October 1, 2019) (approving South Coast attainment plan for 2008 8-hour ozone NAAQS and revised attainment plan for 1997 8-hour ozone NAAQS).

[173] CARB Resolution 19–26, paras. A.1, A.2, A.5, and A.6.

[174] Id.

Comment 14: Earthjustice states that there is no reason that these equipment replacements cannot be required by regulation, and that cleaner equipment clearly exists. Earthjustice claims that the only policy issue appears to be who should pay for these replacements, but that nothing stops the agencies from mandating these replacements and providing financial support for compliance. Earthjustice states that the replacements would then become enforceable regulatory requirements and the state and federal agencies could continue to subsidize the agricultural industry as they always have. According to Earthjustice, this would ensure that the emission reductions would occur regardless of future funding and is consistent with the requirements of the Act. Earthjustice urges the EPA to disapprove the Valley Incentive Measure as failing to comply with the Act's basic SIP requirements and to direct CARB and the District to explore enforceable replacement mandates.

Response 14: Under the Clean Air Act, the EPA is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations.[175] 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. These comments are more appropriately directed to CARB during its rulemaking processes on incentive-based measures.

IV. Final Action

The EPA is partially approving the Valley Incentive Measure, as amended and clarified by the Technical Corrections Document and the 2021 Clarification Document, into the California SIP in accordance with section 110(k)(3) of the Act. Specifically, the EPA is approving those portions of the Valley Incentive Measure, as amended and clarified, that pertain to incentive projects implemented under California's Carl Moyer Program and FARMER Program, based on our conclusion that these portions of the measure satisfy CAA requirements for SIP approval. Upon our approval of these portions of the Valley Incentive Measure into the SIP, they become enforceable under the CAA and creditable for SIP purposes. The EPA is deferring action on the remaining portions of the Valley Incentive Measure.

In addition, the EPA is determining that CARB's adoption, implementation, and submission of the Valley Incentive Measure satisfies the State's commitment in the SJV $PM_{2.5}$ Plan to bring to the Board for consideration an incentive-based measure for off-road diesel agricultural equipment and achieves 4.83 tpd and 0.24 tpd of the State's 2024 NO_X and $PM_{2.5}$ emission reduction commitments, respectively, as codified in 40 CFR 52.220(c)(536)(ii)(A)(*2*).

We are codifying the approved portions of this measure as additional material in the Code of Federal Regulations, rather than through incorporation by reference, because, under its terms, the measure contains commitments enforceable only against CARB and because the measure is not a substantive rule of general applicability.

V. 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 13563 (76 FR 3821, January 21, 2011);
- 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 an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- 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; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, 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. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. 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 February 25, 2022. 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))

[175] 42 U.S.C. 7410(k); 40 CFR 52.02(a). *See Bethlehem Steel Corp.* v. *Gorsuch,* 742 F.2d 1028, 1036 (7th Cir. 1984) (''The state proposes, . . . the EPA disposes'').

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: December 16, 2021.

Deborah Jordan,

Acting Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended 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 F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(567) to read as follows:

§ 52.220 Identification of plan-in part.

* * * * *

(c) * * *

(567) The following materials were submitted on February 11, 2020, by the Governor's designee.

(i) [Reserved]

(ii) *Additional materials.*

(A) California Air Resources Board.

(*1*) Selected portions of CARB Resolution 19–26, adopted December 12, 2019, as revised and clarified by Executive Order S–20–031, adopted November 23, 2020 and Executive Order S–21–018, adopted October 6, 2021 (Amended Valley Incentive Measure), containing CARB's commitments to achieve 4.83 tpd of NO_X reductions and 0.24 tpd of $PM_{2.5}$ reductions by the beginning of 2024, and 4.46 tpd of NO_X reductions and 0.26 tpd of $PM_{2.5}$ reductions by the beginning of 2025, through implementation of the Carl Moyer Memorial Air Quality Standards Attainment Program, the Funding Agricultural Replacement Measures for Emission Reductions Program, or substitute measures.

(*2*) [Reserved]

(B) [Reserved]

[FR Doc. 2021–27798 Filed 12–23–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2020–0567; FRL–9001–02–R9]

Air Plan Approval; Hawaii; Interstate Transport for the 2015 Ozone NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a state implementation plan (SIP) revision from the State of Hawaii addressing requirements in the Clean Air Act (CAA or ''Act'') regarding interstate transport for the 2015 ozone national ambient air quality standards (NAAQS). Hawaii submitted a SIP revision on November 12, 2019, addressing the CAA provision prohibiting any source or other type of emissions activity in one state from emitting any air pollutant in amounts that will contribute significantly to nonattainment or interfere with maintenance of the NAAQS in any other state (the ''good neighbor'' provision). The EPA is finalizing approval of Hawaii's good neighbor SIP revision for the 2015 ozone NAAQS.

DATES: This rule is effective on January 26, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2020–0567. 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: Thomas Kelly, Air Planning Office (AIR–2), EPA Region IX, (415) 972–3856, *kelly.thomasp@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

Table of Contents

I. Summary of Proposed Action

On September 28, 2021, the EPA published a notice of proposed rulemaking (NPRM or ''proposed rule'') for the State of Hawaii.[1] We proposed approval of the Hawaii SIP revision that addresses the CAA requirement prohibiting emissions from one state in amounts which significantly contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in any other state. The Hawaii Department of Health (HDOH) submitted its good neighbor SIP revision for the 2015 ozone NAAQS by letter dated November 12, 2019.[2]

We proposed to find that Hawaii would not significantly contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in any other state. The rationale for EPA's proposed rule is provided in the NPRM.

II. Public Comments

Our September 28, 2021 proposed rule provided a 30-day public comment period that closed on October 28, 2021. We received no adverse comments. One anonymous commenter supported the proposed action.

III. Final Action

The EPA is approving, as a revision to the Hawaii SIP, HDOH's good neighbor SIP revision submitted on November 12, 2019. This revision is approved as meeting CAA section 110(a)(2)(D)(i)(I) requirements that emissions from each state do not contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in any other state.

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 final rule merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those

[1] 86 FR 53571.

[2] Letter dated November 12, 2019, from Bruce Anderson, Ph.D., Director of Health, HDOH, to Mike Stoker, Regional Administrator, U.S. EPA, Region IX.

imposed by state law. For that reason, this final rule:

- 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 13563 (76 FR 3821, January 21, 2011);
- 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 an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- 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; and
- Does not provide the EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

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).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, 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. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. 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 February 25, 2022. 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, Infrastructure SIP, Interstate transport, Nitrogen oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: December 15, 2021.

Deborah Jordan,

Acting Regional Administrator, Region IX.

Chapter I, title 40 of the Code of Federal Regulations is amended 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 M—Hawaii

■ 2. In § 52.620, amend the table in paragraph (e) by adding an entry for ''Hawaii State Implementation Plan Revision to address CAA 110(a)(2)(D)(i)(I) for the 2015 Ozone National Ambient Air Quality Standards'' immediately after the entry for ''Hawaii State Implementation Plan Revision to Address CAA Section 110(a)(2)(D)(i)(I) for the 2008 Ozone National Ambient Air Quality Standard, excluding Attachment 3'' to read as follows:

§ 52.620 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED HAWAII NONREGULATORY AND QUASI-REGULATORY MEASURES

Name of SIP provision	Applicable geographic or nonattainment area or title/ subject	State submittal date	EPA approval date	Explanation
*	* *	*	*	*
State of Hawaii Air Pollution Control Implementation Plans for Nitrogen Dioxide, Ozone, $PM_{2.5}$, and Lead				
*	* *	*	*	*
Hawaii State Implementation Plan Revision to address CAA 110(a)(2)(D)(i)(I) for the 2015 Ozone National Ambient Air Quality Standards.	Statewide	November 12, 2019.	December 27, 2021, [Insert **Federal Register** citation].	Approved SIP revision excludes Attachment 2 (''Summary of Public Participation Proceedings'').
*	* *	*	*	*

[FR Doc. 2021–27556 Filed 12–23–21; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[EPA–HQ–OW–2020–0530; FRL–6791–03–OW]

RIN 2040–AF89

Revisions to the Unregulated Contaminant Monitoring Rule (UCMR 5) for Public Water Systems and Announcement of Public Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule and notice of public meetings.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is finalizing a Safe Drinking Water Act (SDWA) rule that requires certain public water systems (PWSs) to collect national occurrence data for 29 per- and polyfluoroalkyl substances (PFAS) and lithium. Subject to the availability of appropriations, EPA will include all systems serving 3,300 or more people and a representative sample of 800 systems serving 25 to 3,299 people. If EPA does not receive the appropriations needed for monitoring all of these systems in a given year, EPA will reduce the number of systems serving 25 to 10,000 people that will be asked to perform monitoring. This final rule is a key action to ensure science-based decision-making and prioritize protection of disadvantaged communities in accordance with EPA's PFAS Strategic Roadmap. EPA is also announcing plans for public webinars to discuss implementation of the fifth Unregulated Contaminant Monitoring Rule (UCMR 5).

DATES: This final rule is effective on January 26, 2022. The incorporation by reference of certain publications listed in this final rule is approved by the Director of the Federal Register as of January 26, 2022.

ADDRESSES: EPA has established a *docket* for this action under Docket ID No. EPA–HQ–OW–2020–0530. 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.,* 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 electronically through *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Brenda D. Bowden, Standards and Risk Management Division (SRMD), Office of Ground Water and Drinking Water (OGWDW) (MS 140), Environmental Protection Agency, 26 West Martin Luther King Drive, Cincinnati, Ohio 45268; telephone number: (513) 569–7961; email address: *bowden.brenda@epa.gov;* or Melissa Simic, SRMD, OGWDW (MS 140), Environmental Protection Agency, 26 West Martin Luther King Drive, Cincinnati, Ohio 45268; telephone number: (513) 569–7864; email address: *simic.melissa@epa.gov.* For general information, visit the Ground Water and Drinking Water web page at: *https://www.epa.gov/ground-water-and-drinking-water.*

SUPPLEMENTARY INFORMATION:

Table of Contents

Abbreviations and Acronyms

μg/L Microgram per Liter
11Cl-PF3OUdS 11-chloroeicosafluoro-3-oxaundecane-1-sulfonic Acid
4:2 FTS 1H, 1H, 2H, 2H-perfluorohexane Sulfonic Acid
6:2 FTS 1H, 1H, 2H, 2H-perfluorooctane Sulfonic Acid
8:2 FTS 1H, 1H, 2H, 2H-perfluorodecane Sulfonic Acid
9Cl-PF3ONS 9-chlorohexadecafluoro-3-oxanone-1-sulfonic Acid
ADONA 4,8-dioxa-3H-perfluorononanoic Acid
AES Atomic Emission Spectrometry
ASDWA Association of State Drinking Water Administrators
ASTM ASTM International
AWIA America's Water Infrastructure Act of 2018
CASRN Chemical Abstracts Service Registry Number
CBI Confidential Business Information
CCL Contaminant Candidate List
CCR Consumer Confidence Report
CFR Code of Federal Regulations
CRA Congressional Review Act
CWS Community Water System
DBP Disinfection Byproduct
DWSRF Drinking Water State Revolving Fund
EPA United States Environmental Protection Agency
EPTDS Entry Point to the Distribution System
FR Federal Register
FRB Field Reagent Blank
GW Ground Water
GWRMP Ground Water Representative Monitoring Plan
HFPO-DA Hexafluoropropylene Oxide Dimer Acid (GenX)
HRL Health Reference Level
ICP Inductively Coupled Plasma
ICR Information Collection Request
IDC Initial Demonstration of Capability
LCMRL Lowest Concentration Minimum Reporting Level
LC/MS/MS Liquid Chromatography/Tandem Mass Spectrometry
MDBP Microbial and Disinfection Byproduct
MRL Minimum Reporting Level
NAICS North American Industry Classification System
NCOD National Contaminant Occurrence Database
NDAA National Defense Authorization Act for Fiscal Year 2020
NEtFOSAA N-ethyl Perfluorooctanesulfonamidoacetic Acid
NFDHA Nonafluoro-3,6-dioxaheptanoic Acid
ng/L Nanogram per Liter
NMeFOSAA N-methyl Perfluorooctanesulfonamidoacetic Acid
NPDWR National Primary Drinking Water Regulation
NTNCWS Non-transient Non-community Water System
NTTAA National Technology Transfer and Advancement Act
NTWC National Tribal Water Council
OGWDW Office of Ground Water and Drinking Water
OMB Office of Management and Budget
PFAS Per- and Polyfluoroalkyl Substances
PFBA Perfluorobutanoic Acid
PFBS Perfluorobutanesulfonic Acid
PFDA Perfluorodecanoic Acid
PFDoA Perfluorododecanoic Acid
PFEESA Perfluoro (2-ethoxyethane) Sulfonic Acid
PFHpA Perfluoroheptanoic Acid
PFHpS Perfluoroheptanesulfonic Acid
PFHxA Perfluorohexanoic Acid
PFHxS Perfluorohexanesulfonic Acid
PFMBA Perfluoro-4-methoxybutanoic Acid
PFMPA Perfluoro-3-methoxypropanoic Acid
PFNA Perfluorononanoic Acid
PFOA Perfluorooctanoic Acid
PFOS Perfluorooctanesulfonic Acid
PFPeA Perfluoropentanoic Acid
PFPeS Perfluoropentanesulfonic Acid
PFTA Perfluorotetradecanoic Acid
PFTrDA Perfluorotridecanoic Acid
PFUnA Perfluoroundecanoic Acid
PN Public Notice
PRA Paperwork Reduction Act
PT Proficiency Testing
PWS Public Water System
QC Quality Control
RFA Regulatory Flexibility Act
SBA Small Business Administration
SBREFA Small Business Regulatory Enforcement Fairness Act
SDWA Safe Drinking Water Act
SDWARS Safe Drinking Water Accession and Review System
SDWIS/Fed Safe Drinking Water Information System Federal Reporting Services
SM Standard Methods for the Examination of Water and Wastewater
SOP Standard Operating Procedure
SPE Solid Phase Extraction
SRMD Standards and Risk Management Division
SW Surface Water
SWTR Surface Water Treatment Rule
TNCWS Transient Non-community Water System
TOF Total Organic Fluorine
TOP Total Oxidizable Precursors
UCMR Unregulated Contaminant Monitoring Rule
UMRA Unfunded Mandates Reform Act of 1995
U.S. United States
USEPA United States Environmental Protection Agency

I. Summary Information

A. Purpose of the Regulatory Action

1. What action is EPA taking?

This final rule requires certain public water systems (PWSs), described in section I.A.2 of this preamble, to collect national occurrence data for 29 PFAS and lithium. PFAS and lithium are not currently subject to national primary drinking water regulations, and EPA is requiring collection of data under UCMR 5 to inform EPA regulatory determinations and risk-management decisions. Consistent with EPA's PFAS Strategic Roadmap, UCMR 5 will provide new data critically needed to improve EPA's understanding of the frequency that 29 PFAS (and lithium) are found in the nation's drinking water systems and at what levels. This data will ensure science-based decision-making and help prioritize protection of disadvantaged communities.

2. Does this action apply to me?

This final rule applies to PWSs described in this section. PWSs are systems that provide water for human consumption through pipes, or constructed conveyances, to at least 15 service connections or that regularly serve an average of at least 25 individuals daily at least 60 days out of the year. A community water system (CWS) is a PWS that has at least 15 service connections used by year-round residents or regularly serves at least 25 year-round residents. A non-transient non-community water system (NTNCWS) is a PWS that is not a CWS and that regularly serves at least 25 of the same people over 6 months per year. Under this final rule, all large CWSs and NTNCWSs serving more than 10,000 people are required to monitor. In addition, small CWSs and NTNCWSs serving between 3,300 and 10,000 people are required to monitor (subject to available EPA appropriations and EPA notification of such requirement) as are the PWSs included in a nationally representative sample of CWSs and NTNCWSs serving between 25 and 3,299 people (see ''Selection of Nationally Representative Public Water Systems for the Unregulated Contaminant Monitoring Rule: 2021 Update'' for a description of the statistical approach for EPA's selection of the nationally representative sample (USEPA, 2021a), available in the UCMR 5 public docket). EPA expects to clarify the monitoring responsibilities for affected small systems by approximately July 1 of each year preceding sample collection, based on the availability of appropriations each year.

As in previous UCMRs, transient non-community water systems (TNCWSs) (*i.e.,* non-community water systems that do not regularly serve at least 25 of the same people over 6 months per year) are not required to monitor under UCMR 5. EPA leads UCMR 5 monitoring as a direct-implementation program. States, Territories, and Tribes with primary enforcement responsibility (primacy) to administer the regulatory program for PWSs under SDWA (hereinafter collectively referred to in this document as ''states''), can participate in the implementation of UCMR 5 through voluntary Partnership Agreements (see

discussion of Partnership Agreements in Section III.D of this preamble). Under Partnership Agreements, states can choose to be involved in various aspects of UCMR 5 monitoring for PWSs they oversee; however, the PWS remains responsible for compliance with the final rule. Potentially regulated categories and entities are identified in the following table.

Category	Examples of potentially regulated entities	NAICS *
State, local, & Tribal governments ..	State, local, and Tribal governments that analyze water samples on behalf of PWSs required to conduct such analysis; State, local, and Tribal governments that directly operate CWSs and NTNCWSs required to monitor.	924110
Industry	Private operators of CWSs and NTNCWSs required to monitor	221310
Municipalities	Municipal operators of CWSs and NTNCWSs required to monitor	924110

* NAICS = North American Industry Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your entity is regulated by this action, you should carefully examine the definition of PWS found in Title 40 in the *Code of Federal Regulations* (CFR) at 40 CFR 141.2 and 141.3, and the applicability criteria found in 40 CFR 141.40(a)(1) and (2). If you have questions regarding the applicability of this action to a particular entity, please consult the contacts listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this preamble.

3. What is EPA's authority for taking this action?

As part of EPA's responsibilities under SDWA, the agency implements section 1445(a)(2), Monitoring Program for Unregulated Contaminants. This section, as amended in 1996, requires that once every five years, beginning in August 1999, EPA issue a list of not more than 30 unregulated contaminants to be monitored by PWSs. SDWA requires that EPA enter the monitoring data into the agency's publicly available National Contaminant Occurrence Database (NCOD) at *https://www.epa.gov/sdwa/national-contaminant-occurrence-database-ncod.*

EPA must vary the frequency and schedule for monitoring based on the number of people served, the source of supply, and the contaminants likely to be found. EPA is using SDWA Section 1445(a)(2) authority as the basis for monitoring the unregulated contaminants under this final rule.

Section 2021 of America's Water Infrastructure Act of 2018 (AWIA) (Pub. L. 115–270) amended SDWA and specifies that, subject to the availability of EPA appropriations for such purpose and sufficient laboratory capacity, EPA's UCMR program must require all PWSs serving between 3,300 and 10,000 people to monitor for the contaminants in a particular UCMR cycle, and ensure that only a nationally representative sample of systems serving between 25 and 3,299 people are required to monitor for those contaminants. EPA has developed this final rule anticipating that necessary appropriations will become available; however, to date, Congress has not appropriated additional funding (*i.e.,* funding in addition to the $2.0 million that EPA has historically set aside each year from the Drinking Water State Revolving Fund, using SDWA authority, to support UCMR monitoring at small systems) to cover monitoring expenses for all PWSs serving between 3,300 and 10,000 people. Provisions in the final rule enable the agency to adjust the number of these systems that must monitor based upon available appropriations.

AWIA did not amend the original SDWA requirements for large PWSs. Therefore, PWSs serving a population larger than 10,000 people continue to be responsible for participating in UCMR.

Section 7311 of the National Defense Authorization Act for Fiscal Year 2020 (NDAA) (Pub. L. 116–92) amended SDWA and specifies that EPA shall include all PFAS in UCMR 5 for which a drinking water method has been validated by the Administrator and that are not subject to a national primary drinking water regulation.

4. What is the applicability date?

The applicability date represents an internal milestone used by EPA to determine if a PWS is included in the UCMR program and whether it will be treated as small (*i.e.,* serving 25 to 10,000 people) or large (*i.e.,* serving more than 10,000 people). It does not represent a date by which respondents need to take any action. The determination of whether a PWS is required to monitor under UCMR 5 is based on the type of system (*e.g.,* CWS, NTNCWS, etc.) and its retail population served, as indicated by the Safe Drinking Water Information System Federal Reporting Services (SDWIS/Fed) inventory on February 1, 2021. SDWIS/Fed can be accessed at *https://www.epa.gov/ground-water-and-drinking-water/safe-drinking-water-information-system-sdwis-federal-reporting.* Examining water system type and population served as of February 1, 2021 allowed EPA to develop a draft list of PWSs tentatively subject to UCMR 5 and share that list with the states during 2021 for their review. This advance planning and review then allowed EPA to load state-reviewed PWS information into EPA's reporting system so that those PWSs can be promptly notified upon publication of this final rule. If a PWS receives such notification and believes it has been erroneously included in UCMR 5 based on an incorrect retail population, the system should contact their state authority to verify its population served as of the applicability date. If an error impacting rule applicability is identified, the state or the PWS may contact EPA to address the error. The 5-year UCMR 5 cycle spans January 2022 through December 2026, with preparations in 2022, sample collection between January 1, 2023, and December 31, 2025, and completion of data reporting in 2026. By approximately July 1 of the year prior to each year's sample collection (*i.e.,* by July 1, 2022 for 2023 sampling; by July 1, 2023 for 2024 sampling; and by July 1, 2024 for 2025 sampling) EPA expects to determine whether it has received necessary appropriations to support its plan to monitor at all systems serving between 3,300 and 10,000 people and at a representative group of 800 smaller systems. As EPA finalizes its small-system plan for each sample collection year, the agency will notify the small PWSs accordingly.

B. Summary of the Regulatory Action

EPA is requiring certain PWSs to collect occurrence data for 29 PFAS and lithium. This document addresses key aspects of UCMR 5, including the following: Analytical methods to

measure the contaminants; laboratory approval; monitoring timeframe; sampling locations; data elements (*i.e.,* information required to be collected along with the occurrence data); data reporting timeframes; monitoring cost; public participation; conforming and editorial changes, such as those necessary to remove requirements solely related to UCMR 4; and EPA responses to public comments on the proposed rule. This document also discusses the implication for UCMR 5 of the AWIA Section 2021(a) requirement that EPA collect monitoring data from all systems serving more than 3,300 people ''subject to the availability of appropriations.''

Regardless of whether EPA is able to carry out the small-system monitoring as planned, or instead reduces the scope of that monitoring, the small-system data collection, coupled with data collection from all systems serving more than 10,000 people under this action, will provide scientifically valid data on the national occurrence of 29 PFAS and lithium in drinking water. The UCMR data are the primary source of national occurrence data that EPA uses to inform regulatory and other risk management decisions for drinking water contaminant candidates.

EPA is required under SDWA Section 1445(a)(2)(C)(ii) to pay the ''reasonable cost of such testing and laboratory analysis'' for all applicable PWSs serving 25 to 10,000 people. Consistent with AWIA, EPA will require monitoring at as many systems serving 3,300 to 10,000 people as appropriations support (see Section IV.B of this preamble for more information on the agency's sampling design).

The agency received several public comments expressing concern that significant laboratory capacity will be needed to support the full scope envisioned for UCMR 5 PFAS monitoring. EPA anticipates that sufficient laboratory capacity will exist to support the expanded UCMR 5 scope. EPA's experience over the first four cycles of UCMR implementation has been that laboratory capacity quickly grows to meet UCMR demand. EPA also notes that the number of laboratories successfully participating in the early stages of the UCMR 5 laboratory approval program is a good indicator that there will be a robust national network of laboratories experienced in PFAS drinking water analysis.

By early 2022, EPA will notify all small CWSs and NTNCWSs serving between 3,300 and 10,000 people of their anticipated requirement to monitor, which EPA expects to confirm and schedule by July 1 preceding each collection year based on the availability of appropriations. The nationally representative sample of smaller PWSs described in Section I.A of this preamble will be similarly notified and advised of their schedules.

This final rule addresses the requirements of the NDAA by including all 29 PFAS that are within the scope of EPA Methods 533 and 537.1. Both of these methods have been validated by EPA for drinking water analysis.

C. Economic Analysis

1. What is the estimated cost of this action?

EPA estimates the total average national cost of this action would be $21 million per year over the 5-year effective period of the final rule (2022–2026) assuming EPA collects information from all systems serving between 3,300 and 10,000 people. All of these costs are associated with paperwork burden under the Paperwork Reduction Act (PRA). EPA discusses the expected costs as well as documents the assumptions and data sources used in the preparation of this estimate in the ''Information Collection Request for the Final Unregulated Contaminant Monitoring Rule (UCMR 5)'' (USEPA, 2021b). Costs are incurred by large PWSs (for sampling and analysis); small PWSs (for sampling); state regulatory agencies (*i.e.,* those who volunteer to assist EPA with oversight and implementation support); and EPA (for regulatory support and oversight activities, and analytical and shipping costs for samples from small PWSs). These costs are also summarized in Exhibit 1 of this preamble. EPA's estimates are based on executing the full monitoring plan for small systems (*i.e.,* including all systems serving 3,300 to 10,000 people and a representative group of 800 smaller systems). As such, those estimates represent an upper bound. If EPA does not receive the necessary appropriations in one or more of the collections years—and thus collects data from fewer small systems—the actual costs would be lower than those estimated here.

EPA received several comments on the cost of monitoring. EPA has accounted for the cost/burden associated with all of the PWS activities as part of the comprehensive cost/burden estimates. In order to provide the most accurate and updated cost estimate, EPA re-examined labor burden estimates for states, EPA, and PWS activities and updated costs of laboratory services for sample analysis, based on consultations with national drinking water laboratories, when developing this final rule.

The costs for a particular UCMR cycle are heavily influenced by the selection of contaminants and associated analytical methods. EPA identified three EPA-developed analytical methods (and, in the case of lithium, multiple optional alternative methods) to analyze samples for UCMR 5 contaminants. EPA's estimate of the UCMR 5 analytical cost is $740 per sample set (*i.e.,* $740 to analyze a set of samples from one sample point and one sample event for the 30 UCMR 5 contaminants).

Exhibit 1 of this preamble details the EPA-estimated annual average national costs (accounting for labor and non-labor expenses). Laboratory analysis and sample shipping account for approximately 65 percent of the estimated total national cost for the implementation of UCMR 5. EPA estimated laboratory costs based on consultations with multiple commercial drinking water testing laboratories. EPA's cost estimates for the laboratory methods include shipping and analysis.

EPA expects that states will incur modest labor costs associated with voluntary assistance with the implementation of UCMR 5. EPA estimated state costs using the relevant assumptions from the State Resource Model developed by the Association of State Drinking Water Administrators (ASDWA) (ASDWA, 2013) to help states forecast resource needs. Model estimates were adjusted to account for actual levels of state participation under UCMR 4. State assistance with EPA's implementation of UCMR 5 is voluntary; thus, the level of effort is expected to vary among states and will depend on their individual agreements with EPA.

EPA assumes that one-third of the systems will collect samples during each of the three sample-collection years from January 2023 through December 2025.

EXHIBIT 1—ESTIMATED AVERAGE ANNUAL COSTS OF UCMR 5 [1]

Entity	Average annual cost (million) (2022–2026) [2]
Small PWSs (25–10,000), including labor [3] only (non-labor costs [4] paid for by EPA)	$0.3
Large PWSs (10,001–100,000), including labor and non-labor costs	7.0
Very Large PWSs (100,001 and greater), including labor and non-labor costs	2.2
States, including labor costs related to implementation coordination	0.8
EPA, including labor for implementation and non-labor for small system testing	[5] 10.5
Average Annual National Total	20.8

[1] Based on the scope of small-system monitoring described in AWIA.
[2] Totals may not equal the sum of components due to rounding.
[3] Labor costs pertain to PWSs, states, and EPA. Costs include activities such as reading the final rule, notifying systems selected to participate, sample collection, data review, reporting, and record keeping.
[4] Non-labor costs will be incurred primarily by EPA and by large and very large PWSs. They include the cost of shipping samples to laboratories for testing and the cost of the laboratory analyses.
[5] For a typical UCMR program that involves the expanded scope prescribed by AWIA, EPA estimates an average annual cost to the agency of $17M/year (over a 5-year cycle) ($2M/year for the representative sample of 800 PWSs serving between 25 and 3,299 people and $15M/year for all PWSs serving between 3,300 and 10,000 people). The projected cost to EPA for UCMR 5 implementation is lower than for a typical UCMR program because of lower sample analysis expenses. Those lower expenses are a result of analytical method efficiencies (*i.e.,* being able to monitor for 30 chemicals with only three analytical methods).

Additional details regarding EPA's cost assumptions and estimates can be found in the Information Collection Request (ICR) (USEPA, 2021b), ICR Number 2040–0304, which presents estimated cost and labor hours for the 5-year UCMR 5 period of 2022–2026. Copies of the ICR may be obtained from the EPA public docket for this final rule under Docket ID No. EPA–HQ–OW–2020–0530.

2. What are the benefits of this action?

The public benefits from the information about whether or not unregulated contaminants are present in their drinking water. If contaminants are not found, consumer confidence in their drinking water should improve. If contaminants are found, related health effects may be avoided when subsequent actions, such as regulations, are implemented, reducing or eliminating those contaminants.

II. Public Participation

A. What meetings have been held in preparation for UCMR 5?

EPA held three public meetings on UCMR 5 over the period of 2018 through 2021. EPA held a meeting focused on drinking water methods for unregulated contaminants on June 6, 2018, in Cincinnati, Ohio. Representatives from state agencies, laboratories, PWSs, environmental organizations, and drinking water associations joined the meeting via webinar and in person. Meeting topics included an overview of regulatory process elements (including the Contaminant Candidate List (CCL), UCMR, and Regulatory Determination), and drinking water methods under development (see USEPA, 2018 for presentation materials). EPA held a second meeting on July 16, 2019, in Cincinnati, Ohio. Representatives from State agencies, Tribes, laboratories, PWSs, environmental organizations, and drinking water associations participated in the meeting via webinar and in person. Meeting topics included the impacts of AWIA, analytical methods and contaminants being considered by EPA, potential sampling design, and other possible aspects of the UCMR 5 approach (see USEPA, 2019a for meeting materials). EPA held two identical virtual meetings on April 6 and 7, 2021, during the public comment period for the proposed rule (see USEPA, 2021c for presentation materials). Topics included the proposed UCMR 5 monitoring requirements, analyte selection and rationale, analytical methods, the laboratory approval process, and ground water representative monitoring plans (GWRMPs). Representatives of state agencies, laboratories, PWSs, environmental organizations, and drinking water associations participated in the meeting via webinar. In Section II.B of this preamble, the agency is announcing additional meetings to be held in 2022, which will assist with implementation.

B. How do I participate in the upcoming meetings?

EPA will hold multiple virtual meetings during 2022 to discuss UCMR 5 implementation planning, data reporting using Safe Drinking Water Accession and Review System (SDWARS), and best practices for sample collection. Dates and times of the upcoming meetings will be posted on EPA's website at *https://www.epa.gov/dwucmr/unregulated-contaminant-monitoring-rule-ucmr-meetings-and-materials.* EPA anticipates hosting the meetings focused on implementation planning in spring 2022, and the SDWARS and sample-collection meetings in fall 2022. Stakeholders who have participated in past UCMR meetings and/or those who register to use SDWARS will receive notification of these events. Other interested stakeholders are also welcome to participate.

1. Meeting Participation

Those who wish to participate in the public meetings, via webinar, can find information on how to register at *https://www.epa.gov/dwucmr/unregulated-contaminant-monitoring-rule-ucmr-meetings-and-materials.* The number of webinar connections available for the meetings are limited and will be available on a first-come, first-served basis. If stakeholder interest results in exceeding the maximum number of available connections for participants in upcoming webinar offerings, EPA may schedule additional webinars, with dates and times posted on EPA's Unregulated Contaminant Monitoring Program Meetings and Materials web page at *https://www.epa.gov/dwucmr/unregulated-contaminant-monitoring-rule-ucmr-meetings-and-materials.*

2. Meeting Materials

EPA expects to send meeting materials by email to all registered participants prior to the meeting. The materials will be posted on EPA's website at *https://www.epa.gov/dwucmr/unregulated-contaminant-*

monitoring-rule-ucmr-meetings-and-materials for people who do not participate in the webinar.

III. General Information

A. How are CCL, UCMR, Regulatory Determination process, and NCOD interrelated?

Under the 1996 amendments to SDWA, Congress established a multi-step, risk-based approach for determining which contaminants would become subject to drinking water standards. Under the first step, EPA is required to publish a CCL every five years that identifies contaminants that are not subject to any proposed or promulgated drinking water regulations, are known or anticipated to occur in PWSs, and may require future regulation under SDWA. EPA published the draft CCL 5 in the **Federal Register** on July 19, 2021 (86 FR 37948, July 19, 2021 (USEPA, 2021d)). Under the second step, EPA must require, every five years, monitoring of unregulated contaminants as described in this action. The third step requires EPA to determine, every five years, whether or not to regulate at least five contaminants from the CCL. Under Section 1412(b)(1)(A) of SDWA, EPA regulates a contaminant in drinking water if the Administrator determines that:

(1) The contaminant may have an adverse effect on the health of persons;

(2) The contaminant is known to occur or there is substantial likelihood that the contaminant will occur in PWSs with a frequency and at levels of public health concern; and

(3) In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs.

For the contaminants that meet all three criteria, SDWA requires EPA to publish national primary drinking water regulations (NPDWRs). Information on the CCL and the regulatory determination process can be found at: *https://www.epa.gov/ccl.*

The data collected through the UCMR program are made available to the public through the National Contaminant Occurrence Database (NCOD) for drinking water. EPA developed the NCOD to satisfy requirements in SDWA Section 1445(g), to assemble and maintain a drinking water contaminant occurrence database for both regulated and unregulated contaminants in drinking water systems. NCOD houses data on unregulated contaminant occurrence; data from EPA's ''Six-Year Review'' of national drinking water regulations; and ambient and/or source water data. Section 1445(g)(3) of SDWA requires that EPA maintain UCMR data in the NCOD and use the data when evaluating the frequency and level of occurrence of contaminants in drinking water at a level of public health concern. UCMR results can be viewed by the public via NCOD (*https://www.epa.gov/sdwa/national-contaminant-occurrence-database-ncod*) or via the UCMR web page at: *https://www.epa.gov/dwucmr.*

B. What are the Consumer Confidence Reporting and Public Notice Reporting requirements for public water systems that are subject to UCMR?

In addition to reporting UCMR monitoring data to EPA, PWSs are responsible for presenting and addressing UCMR results in their annual Consumer Confidence Reports (CCRs) (40 CFR 141.153) and must address Public Notice (PN) requirements associated with UCMR (40 CFR 141.207). More details about the CCR and PN requirements can be viewed by the public at: *https://www.epa.gov/ccr* and *https://www.epa.gov/dwreginfo/public-notification-rule,* respectively.

C. What is the UCMR 5 timeline?

This final rule identifies a UCMR 5 sampling period of 2023 to 2025. Prior to 2023 EPA will coordinate laboratory approval, tentatively select representative small systems (USEPA, 2021a), organize Partnership Agreements, develop State Monitoring Plans (see Section III.D of this preamble), establish monitoring schedules and inventory, and conduct outreach and training. Exhibit 2 of this preamble illustrates the major activities that EPA expects will take place in preparation for and during the implementation of UCMR 5.

BILLING CODE 6560–50–P

Exhibit 2: Timeline of UCMR 5 Activities

2022	2023	2024	2025	2026
Pre-sampling Activity by EPA, States[1] • EPA manages Laboratory Approval Program • EPA organizes Partnership Agreements and State Monitoring Plans • EPA/States notify affected PWSs of UCMR 5 monitoring plan following final rule publication • EPA/States send SDWARS registrations • EPA/States review GWRMP submittals • EPA conducts outreach/trainings • EPA confirms sample collection by mid-2022 with small systems scheduled for 2023 monitoring. **Pre-sampling Activity by PWSs** • Register for a SDWARS account and provide sampling location inventory and contact information	← **Sampling Period** →			**Post-sampling Activity** **PWSs, Laboratories** • Complete resampling, as needed • Conclude data reporting **EPA** • Complete upload of UCMR 5 data to NCOD
	EPA, State[1] **Implementation Activities** • EPA, State provide compliance assistance • EPA, State implement small system monitoring • EPA posts data quarterly to NCOD • EPA confirms sample collection by mid-2023 (for small systems scheduled for 2024 monitoring) and by mid-2024 (for small systems scheduled for 2025 monitoring) **PWS Sample Collection; Laboratory Analysis; Reporting (~1/3 in each year)** • All large systems serving more than 10,000 people • All small systems serving between 3,300 and 10,000 people, if confirmed by EPA • Up to 800 small systems serving between 25 and 3,299 people, as confirmed by EPA			

[1] State participation is defined in voluntary Partnership Agreements with EPA</PHOTO>

BILLING CODE 6560–50–C

D. What is the role of ''States'' in UCMR?

UCMR is a direct implementation rule (*i.e.,* EPA has primary responsibility for its implementation) and state participation is voluntary. Under the previous UCMR cycles, specific activities that individual states agreed to carry out or assist with were identified and established exclusively through Partnership Agreements. Through Partnership Agreements, states can help EPA implement UCMR and help ensure that the UCMR data are of the highest quality possible to best support the agency decision making. Under UCMR 5, EPA will continue to use the Partnership Agreement process to determine and document the following:

The process for review and revision of the State Monitoring Plans; replacing and updating PWS information, including inventory (*i.e.,* PWS identification codes (PWSID), facility identification code along with associated facility types and water source type, etc.); review of proposed GWRMPs; notification and instructions for systems; and compliance assistance. EPA recognizes that states often have the best information about their PWSs and encourages them to partner in the UCMR 5 program.

E. How did EPA consider Children's Environmental Health?

By monitoring for unregulated contaminants that may pose health risks via drinking water, UCMR furthers the protection of public health for all citizens, including children. Children consume more water per unit of body weight compared to adults. Moreover, formula-fed infants drink a large amount of water compared to their body weight; thus, children's exposure to contaminants in drinking water may present a disproportionate health risk (USEPA, 2011). The objective of UCMR 5 is to collect nationally representative drinking water occurrence data on unregulated contaminants for future regulatory consideration. Information on the prioritization process, as well as contaminant-specific information (*e.g.,* source, use, production, release, persistence, mobility, health effects, and occurrence), that EPA used to select the analyte list, is contained in ''Information Compendium for Contaminants for the Final Unregulated Contaminant Monitoring Rule (UCMR 5)'' (USEPA, 2021e), available in the UCMR 5 public docket.

Since this is a final rule to monitor for contaminants and not to reduce their presence in drinking water to an acceptable level, the rule does not concern environmental health or safety risks presenting a disproportionate risk to children that would be addressed by this action (See Section V.G Executive Order 13045 of this preamble). Therefore, Executive Order 13045 does not apply to UCMR. However, EPA's *Policy on Evaluating Health Risks to Children,* which ensures that the health of infants and children is explicitly considered in the agency's decision making, is applicable, see: *https://www.epa.gov/children/epas-policy-evaluating-risk-children.*

EPA considered children's health risks during the development of UCMR 5. This included considering public comments about candidate contaminant priorities. Many commenters supported the agency's inclusion of PFAS and lithium in UCMR 5. Some commenters requested that EPA consider children and infant health risks in its risk communication for UCMR 5.

Using quantitation data from multiple laboratories, EPA establishes statistically-based UCMR reporting levels the agency considers feasible for the national network of approved drinking water laboratories. EPA generally sets the reporting levels as low as is technologically practical for measurement by that national network of laboratories, even if that level is well below concentrations that are currently associated with known or suspected health effects. In doing so, EPA positions itself to better address contaminant risk information in the future, including that associated with unique risks to children.

F. How did EPA address Environmental Justice (EJ)?

EPA has concluded that this action is not subject to Executive Order 12898 because it does not establish an environmental health or safety standard (see Section V.J Executive Order 12898 of this preamble). EPA Administrator Regan issued a directive to all EPA staff to incorporate environmental justice (EJ) into the agency's work, including regulatory activities, such as integrating EJ considerations into the regulatory development processes and considering regulatory options to maximize benefits to communities that ''continue to suffer from disproportionately high pollution levels and the resulting adverse health and environmental impacts.'' In keeping with this directive, and consistent with AWIA, EPA will, subject to the availability of sufficient appropriations, expand UCMR 5 to include all PWSs serving between 3,300 and 10,000 people as described in Sections I.A.4 and IV.B of this preamble. If there are sufficient appropriations, the expansion in the number of participating PWSs will provide a more comprehensive assessment of contaminant occurrence data from small and rural communities, including disadvantaged communities.

By developing a national characterization of unregulated contaminants that may pose health risks via drinking water from PWSs, UCMR furthers the protection of public health for all citizens. If EPA receives the needed appropriations, the expansion in monitoring scope reflected in UCMR 5 (*i.e.,* including all PWSs serving 3,300 to 10,000 people) will better support state and regional analyses and determination of potential EJ-related issues that need to be addressed. EPA structured the UCMR 5 rulemaking process to allow for meaningful involvement and transparency. EPA organized public meetings and webinars to share information regarding the development and implementation of UCMR 5; consulted with Tribal governments; and convened a workgroup that included representatives from several states. EPA will support stakeholder interest in UCMR 5 results by making them publicly available, as described in Section III.A of this preamble, and by developing additional risk-communication materials to help individuals and communities understand the significance of contaminant occurrence.

EPA received multiple comments on environmental justice considerations. Commenters expressed support for the continued collection of U.S. Postal Service Zip Codes for each PWS's service area and requested that EPA provide multilingual UCMR materials. EPA will continue to collect Zip Codes for UCMR 5, as collected under UCMR 3 and UCMR 4, to support potential assessments of whether or not certain communities are disproportionately impacted by particular drinking water contaminants. EPA also intends to develop the sampling instructions, fact sheets, and data summaries in both English and Spanish.

G. How did EPA coordinate with Indian Tribal Governments?

EPA has concluded that this action has Tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized Tribal governments, nor preempt Tribal law. (See section V.F Executive Order 13175 of this preamble).

EPA consulted with Tribal officials under the *EPA Policy on Consultation and Coordination with Indian Tribes* early in the process of developing this action to ensure meaningful and timely input into its development. EPA initiated the Tribal consultation and coordination process before proposing the rule by mailing a ''Notification of Consultation and Coordination'' letter on June 26, 2019, to the Tribal leadership of the then 573 federally recognized Tribes. The letter invited Tribal leaders and representatives of Tribal governments to participate in an August 6, 2019, UCMR 5 Tribal consultation and coordination informational meeting. Presentation topics included an overview of the UCMR program, potential approaches to monitoring and implementation for UCMR 5, and the UCMR 5 contaminants and analytical methods under consideration. After the presentation, EPA provided an opportunity for input

and questions on the action. Eight representatives from five Tribes attended the August meeting. Tribal representatives asked clarifying questions regarding program costs to PWSs and changes in PWS participation per AWIA. EPA addressed the questions during the meeting. Following the meeting, EPA received and addressed one additional clarifying question from a Tribal representative during the Tribal consultation process. No other Tribal representatives submitted written comments during the UCMR 5 consultation comment period that ended September 1, 2019.

Prior to the August 2019 meeting, EPA provided additional opportunities for Tribal officials to provide meaningful and timely input into the development of the proposed rule. On July 10, 2019, EPA participated in a monthly conference call with the National Tribal Water Council (NTWC). EPA shared a brief summary of UCMR statutory requirements with the Council and highlighted the upcoming official Tribal meeting. EPA also invited Tribal leaders and representatives to participate in a public meeting, held on July 16, 2019, to discuss the development of the proposed rule. Representatives from six Tribes participated in the public meeting. Following the publication of the proposal, EPA advised the Indian Health Services of the 60-day public comment period to assist with facilitating additional Tribal comments on the proposed rule. EPA received no public comments from Tribal officials.

A complete summary of the consultation, titled, ''Summary of the Tribal Coordination and Consultation Process for the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) Proposal,'' is provided in the UCMR 5 public docket listed in the **ADDRESSES** section of this preamble.

H. How are laboratories approved for UCMR 5 analyses?

Consistent with prior UCMRs, this action maintains the requirement that PWSs use laboratories approved by EPA to analyze UCMR 5 samples. Interested laboratories are encouraged to apply for EPA approval as early as possible. The UCMR 5 laboratory approval process, which began with the publication of the UCMR 5 proposal, is designed to assess whether laboratories possess the required equipment and can meet laboratory-performance and data-reporting criteria described in this action.

EPA expects demand for laboratory support to increase significantly based on the greater number of PWSs expected to participate in UCMR 5. EPA anticipates that the number of participating small water systems will increase from the typical 800 to approximately 6,000 (see Exhibit 5 in Section IV.B of this preamble). In preparation for this increase, EPA will solicit proposals and award contracts to laboratories to support small system monitoring prior to the end of the proficiency testing (PT) program. As in previous UCMR programs, EPA expects that laboratories awarded contracts by EPA will be required to first be approved to perform all methods. The requirements for the laboratory approval process are described in steps 1 through 6 of the following paragraphs.

EPA will require laboratories seeking approval to: (1) Provide EPA with data documenting an initial demonstration of capability (IDC) as outlined in each method; (2) verify successful performance at or below the minimum reporting levels (MRLs) as specified in this action; (3) provide information about laboratory standard operating procedures (SOPs); and (4) participate in two EPA PT studies for the analytes of interest. Audits of laboratories may be conducted by EPA prior to and/or following approval, and maintaining approval is contingent on timely and accurate reporting. The ''UCMR 5 Laboratory Approval Manual'' (USEPA, 2021f), available in the UCMR 5 public docket, provides more specific guidance on EPA laboratory approval program and the specific method acceptance criteria. EPA has included sample-collection procedures that are specific to the methods in the ''UCMR 5 Laboratory Manual,'' and will address these procedures in our outreach to the PWSs that will be collecting samples.

The UCMR 5 laboratory approval program will provide an assessment of the ability of laboratories to perform analyses using the methods listed in 40 CFR 141.40(a)(3), Table 1 of this preamble. Laboratory participation in the program is voluntary. However, as in the previous UCMRs, EPA will require PWSs to exclusively use laboratories that have been approved under the program. EPA will post a list of approved UCMR 5 laboratories to *https://www.epa.gov/dwucmr* and will bring this to the attention of the PWSs in our outreach.

1. Request To Participate

Laboratories interested in the UCMR 5 laboratory approval program first email EPA at: *UCMR_Lab_Approval@epa.gov* to request registration materials. EPA began accepting requests beginning with the publication of the proposal in the **Federal Register**.

2. Registration

Laboratory applicants provide registration information that includes laboratory name, mailing address, shipping address, contact name, phone number, email address, and a list of the UCMR 5 methods for which the laboratory is seeking approval. This registration step provides EPA with the necessary contact information and ensures that each laboratory receives a customized application package.

3. Application Package

Laboratory applicants will complete and return a customized application package that includes the following: IDC data, including precision, accuracy, and results of MRL studies; information regarding analytical equipment and other materials; proof of current drinking water laboratory certification (for select compliance monitoring methods); method-specific SOPs; and example chromatograms for each method under review.

As a condition of receiving and maintaining approval, the laboratory must promptly post UCMR 5 monitoring results and quality control data that meet method criteria (on behalf of its PWS clients) to EPA's UCMR electronic data reporting system, SDWARS.

Based on the January 1, 2023 start for UCMR 5 sample collection, the deadline for a laboratory to submit the necessary registration and application information is August 1, 2022.

4. EPA's Review of Application Package

EPA will review the application packages and, if necessary, request follow-up information. Laboratories that successfully complete the application process become eligible to participate in the UCMR 5 PT program.

5. Proficiency Testing

A PT sample is a synthetic sample containing a concentration of an analyte or mixture of analytes that is known to EPA, but unknown to the laboratory. To be approved, a laboratory must meet specific acceptance criteria for the analysis of a UCMR 5 PT sample(s) for each analyte in each method, for which the laboratory is seeking approval. EPA offered three PT studies between publication of the proposed rule and final rule, and anticipates offering at least two additional studies. Interested laboratories must participate in and report data for at least two PT studies. This allows EPA to collect a robust dataset for PT results, and provides laboratories with extra analytical experience using UCMR 5 methods. Laboratories must pass a PT for every analyte in the method to be approved

for that method and may participate in multiple PT studies in order to produce passing results for each analyte. EPA has taken this approach in UCMR 5, recognizing that EPA Method 533 contains 25 analytes. EPA does not expect to conduct additional PT studies after the start of PWS monitoring; however, EPA expects to conduct laboratory audits (remote and/or on-site) throughout the implementation of UCMR 5 on an as needed and/or random basis. Initial laboratory approval is contingent on successful completion of PT studies, which includes properly uploading the PT results to SDWARS. Continued laboratory approval is contingent on successful completion of the audit process and satisfactorily meeting all the other stated conditions.

6. Written EPA Approval

For laboratories that have already successfully completed steps 1 through 5, EPA sent the laboratory a notification letter listing the methods for which approval was ''pending'' (*i.e.,* pending promulgation of this final rule). Because no changes have been made to the final rule that impact the laboratory approval program, laboratories that received pending-approval letters will be notified of full approval without further action on their part. Approval actions for additional laboratories that successfully complete steps 1 through 5 will also be documented by EPA in writing.

I. What documents are being incorporated by reference?

The following methods are being incorporated by reference into this section for UCMR 5 monitoring. All method material is available for inspection electronically at *https://www.regulations.gov* (Docket ID No. EPA–HQ–OW–2020–0530), or from the sources listed for each method. The methods that may be used to support monitoring under this final rule are as follows:

1. Methods From the U.S. Environmental Protection Agency

The following methods are available at EPA's Docket No. EPA–HQ–OW–2020–0530.

(i) EPA Method 200.7 ''Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,'' Revision 4.4, 1994. Available at *https://www.epa.gov/esam/method-2007-determination-metals-and-trace-elements-water-and-wastes-inductively-coupled-plasma.* This is an EPA method for the analysis of metals and trace elements in water by ICP–AES and may be used to measure lithium during UCMR 5. See also the discussion of non-EPA alternative methods for lithium in this section.

(ii) EPA Method 533 ''Determination of Per- and Polyfluoroalkyl Substances in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry,'' November 2019, EPA 815–B–19–020. Available at *https://www.epa.gov/dwanalyticalmethods/analytical-methods-developed-epa-analysis-unregulated-contaminants.* This is an EPA method for the analysis PFAS in drinking water using SPE and LC/MS/MS and is to be used to measure 25 PFAS during UCMR 5 (11Cl-PF3OUdS, 8:2 FTS, 4:2 FTS, 6:2 FTS, ADONA, 9Cl-PF3ONS, HFPO–DA (GenX), NFDHA, PFEESA, PFMPA, PFMBA, PFBS, PFBA, PFDA, PFDoA, PFHpS, PFHpA, PFHxS, PFHxA, PFNA, PFOS, PFOA, PFPeS, PFPeA, and PFUnA).

(iii) EPA Method 537.1 ''Determination of Selected Per- and Polyfluorinated Alkyl Substances in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS),'' Version 2.0, March 2020, EPA/600/R–20/006. Available at *https://www.epa.gov/dwanalyticalmethods/analytical-methods-developed-epa-analysis-unregulated-contaminants.* This is an EPA method for the analysis of PFAS in drinking water using SPE and LC/MS/MS and is to be used to measure four PFAS during UCMR 5 (NEtFOSAA, NMeFOSAA, PFTA, and PFTrDA).

2. Alternative Methods From American Public Health Association—Standard Methods (SM)

The following methods are from American Public Health—Standard Methods (SM), 800 I Street NW, Washington, DC 20001–3710.

(i) ''Standard Methods for the Examination of Water & Wastewater,'' 23rd edition (2017).

(a) SM 3120 B, ''Metals by Plasma Emission Spectroscopy (2017): Inductively Coupled Plasma (ICP) Method.'' This is a Standard Method for the analysis of metals in water and wastewater by emission spectroscopy using ICP and may be used for the analysis of lithium.

(ii) ''Standard Methods Online,'' approved 1999. Available for purchase at *https://www.standardmethods.org.*

(a) SM 3120 B, ''Metals by Plasma Emission Spectroscopy: Inductively Coupled Plasma (ICP) Method, Standard Methods Online,'' revised December 14, 2020. This is a Standard Method for the analysis of metals in water and wastewater by emission spectroscopy using ICP and may be used for the analysis of lithium.

3. Methods From ASTM International

The following methods are from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959.

(i) ASTM D1976–20, ''Standard Test Method for Elements in Water by Inductively-Coupled Plasma Atomic Emission Spectroscopy,'' approved May 1, 2020. Available for purchase at *https://www.astm.org/Standards/D1976.htm.* This is an ASTM method for the analysis of elements in water by ICP–AES and may be used to measure lithium.

IV. Description of Final Rule and Summary of Responses to Public Comments

EPA published ''Revisions to the Unregulated Contaminant Monitoring Rule (UCMR 5) for Public Water Systems and Announcement of Public Meeting;'' Proposed Rule, on March 11, 2021 (86 FR 13846, (USEPA, 2021g)). The UCMR 5 proposal identified three EPA analytical methods, and multiple alternative methods, to support water system monitoring for 30 UCMR 5 contaminants (29 PFAS and lithium) and detailed other potential changes relative to UCMR 4. Among the other changes reflected in the UCMR 5 proposal were the following: Requirement for water systems serving 3,300 to 10,000 people to monitor per AWIA requirements ''subject to the availability of appropriations''; provisions for sampling frequency, timing, and locations; submission timeframe for GWRMPs; data reporting timeframes; and reporting requirements.

EPA received 75 sets of comments from 72 public commenters, including other federal agencies, state and local governments, utilities and utility stakeholder organizations, laboratories, academia, non-governmental organizations, and other interested stakeholders. After considering the comments, EPA developed the final UCMR 5 as described in Exhibit 3 of this preamble. Except as noted, the UCMR 5 final rule approach is consistent with the proposed rule. A track-changes version of the rule language, comparing UCMR 4 to UCMR 5, (''Revisions to 40 CFR 141.35 and 141.40'' (USEPA, 2021h)), is included in the electronic docket listed in the **ADDRESSES** section of this preamble.

This section summarizes key aspects of this final rule and the associated comments received in response to the

proposed rule. EPA has compiled all public comments and EPA's responses in the ''Response to Comments on the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) Proposal,'' (USEPA, 2021i), which can be found in the electronic docket listed in the **ADDRESSES** section of this preamble.

EXHIBIT 3—KEY ELEMENTS OF FINAL UCMR 5

CFR rule section		Description of section	Corresponding preamble section
Number	Title		
40 CFR 141.40(a)(3)	Contaminants in UCMR 5	Maintains proposed list of 29 PFAS and lithium for monitoring	IV.A
40 CFR 141.35(d), 40 CFR 141.40(a)(2)(ii), and 40 CFR 141.40(a)(4)(ii).	Scope of UCMR 5 applicability	Revises the scope of UCMR 5 to reflect that small CWSs and NTNCWSs serving 25 to 10,000 people will monitor (consistent with AWIA), if they are notified by the agency.	IV.B
40 CFR 141.40(a)(i)(B)	Sampling frequency and timing	Maintains proposed sample frequency (four sample events for SW, two sample events for GW).	IV.C
40 CFR 141.35(c)(3)	Sampling locations and Ground Water Representative Monitoring Plans (GWRMPs).	Maintains proposed flexibility for PWSs to submit a GWRMP proposal to EPA.	IV.D
40 CFR 141.35(c)(6)(ii) and 40 CFR 141.40(a)(5)(vi).	Reporting timeframe	Maintains proposed timeframe (''within 90 days from the sample collection date'') for laboratories to post and approve analytical results in EPA's electronic data reporting system (for review by the PWS). Maintains proposed timeframe (''30 days from when the laboratory posts the data to EPA's electronic data reporting system'') for PWSs to review, approve, and submit data to the state and EPA.	IV.E
40 CFR 141.35(e)	Reporting requirements	Removes one proposed data element, maintains 27 proposed data elements, and clarifies the use of state data.	IV.F
40 CFR 141.40(a)(3)	Minimum reporting levels (MRL)	Maintains proposed MRLs for contaminants	IV.G

A. What contaminants must be monitored under UCMR 5?

1. This Final Rule

EPA is maintaining the proposed list of UCMR 5 contaminants and the methods associated with analyzing those contaminants (see Exhibit 4 of this preamble). Further information on the prioritization process, as well as contaminant-specific information (*e.g.,* source, use, production, release, persistence, mobility, health effects, and occurrence), that EPA used to select the analyte list, is contained in ''Information Compendium for Contaminants for the Final Unregulated Contaminant Monitoring Rule (UCMR 5)'' (USEPA, 2021e). This Information Compendium can be found in the electronic docket listed in the **ADDRESSES** section of this preamble.

EXHIBIT 4—UCMR 5 ANALYTES

Twenty-five Per- and Polyfluoroalkyl Substances (PFAS) using EPA Method 533 (SPE LC/MS/MS): [1]	
11-chloroeicosafluoro-3-oxaundecane-1-sulfonic acid (11Cl-PF3OUdS)	perfluorodecanoic acid (PFDA).
1H, 1H, 2H, 2H-perfluorodecane sulfonic acid (8:2 FTS)	perfluorododecanoic acid (PFDoA).
1H, 1H, 2H, 2H-perfluorohexane sulfonic acid (4:2 FTS)	perfluoroheptanesulfonic acid (PFHpS).
1H, 1H, 2H, 2H-perfluorooctane sulfonic acid (6:2 FTS)	perfluoroheptanoic acid (PFHpA).
4,8-dioxa-3H-perfluorononanoic acid (ADONA)	perfluorohexanesulfonic acid (PFHxS).
9-chlorohexadecafluoro-3-oxanone-1-sulfonic acid (9Cl-PF3ONS)	perfluorohexanoic acid (PFHxA).
hexafluoropropylene oxide dimer acid (HFPO–DA) (GenX)	perfluorononanoic acid (PFNA).
nonafluoro-3,6-dioxaheptanoic acid (NFDHA)	perfluorooctanesulfonic acid (PFOS).
perfluoro (2-ethoxyethane) sulfonic acid (PFEESA)	perfluorooctanoic acid (PFOA).
perfluoro-3-methoxypropanoic acid (PFMPA)	perfluoropentanesulfonic acid (PFPeS).
perfluoro-4-methoxybutanoic acid (PFMBA)	perfluoropentanoic acid (PFPeA).
perfluorobutanesulfonic acid (PFBS)	perfluoroundecanoic acid (PFUnA).
perfluorobutanoic acid (PFBA).	
Four Per- and Polyfluoroalkyl Substances (PFAS) using EPA Method 537.1 (SPE LC/MS/MS): [2]	
n-ethyl perfluorooctanesulfonamidoacetic acid (NEtFOSAA)	perfluorotetradecanoic acid (PFTA).
n-methyl perfluorooctanesulfonamidoacetic acid (NMeFOSAA)	perfluorotridecanoic acid (PFTrDA).
One Metal/Pharmaceutical using EPA Method 200.7 (ICP–AES) [3] **or alternate SM** [4] **or ASTM:** [5]	
lithium.	

[1] EPA Method 533 (Solid phase extraction (SPE) liquid chromatography/tandem mass spectrometry (LC/MS/MS)) (USEPA, 2019b).
[2] EPA Method 537.1 Version 2.0 (Solid phase extraction (SPE) liquid chromatography/tandem mass spectrometry (LC/MS/MS)) (USEPA, 2020).
[3] EPA Method 200.7 (Inductively coupled plasma-atomic emission spectrometry (ICP–AES)) (USEPA, 1994).
[4] Standard Methods (SM) 3120 B (SM, 2017) or SM 3120 B–99 (SM Online, 1999).
[5] ASTM International (ASTM) D1976–20 (ASTM, 2020).

2. Summary of Major Comments and EPA Responses

Those who expressed an opinion about the proposed UCMR 5 analytes were supportive of EPA's inclusion of the 29 PFAS and lithium. Commenters expressed mixed opinions on the consideration of additional contaminants, particularly ''aggregate PFAS,'' *Legionella pneumophilia,* haloacetonitriles, and 1,2,3-trichloropropane. The major comments and EPA responses regarding these contaminants are summarized in the discussion that follows.

a. Aggregate PFAS Measure

EPA received multiple comments encouraging the agency to validate and include a total organic fluorine (TOF) and/or total oxidizable precursors (TOP) technique in UCMR 5 as a screening tool to determine ''total PFAS.'' EPA also received comments expressing concern for the limitations of the analytical methodologies, including a lack of sensitivity and specificity for PFAS using TOF.

EPA has not identified a complete, validated, peer-reviewed aggregate PFAS method with the appropriate specificity and sensitivity to support UCMR 5 monitoring. EPA's Office of Water and Office of Research and Development are currently developing and evaluating methodologies for broader PFAS analysis in drinking water, however, the measurement approaches are subject to significant technical challenges. The sensitivity of TOF is currently in the low µg/L range, as opposed to the low ng/L range of interest required for PFAS analysis in drinking water. TOF is also not specific to PFAS. TOP, while focusing on PFAS, is limited to measuring compounds that can be detected by LC/MS/MS and the technique requires two LC/MS/MS analyses; one before oxidation and one after oxidation. EPA is evaluating the TOP approach to understand the degree to which certain precursors are oxidized, and subsequently measurable by LC/MS/MS, as well as the degree to which PFAS that were measured in the pre-oxidation sample are still measured post-oxidation.

EPA is also monitoring progress by commercial laboratories and academia. In 2020 and 2021, EPA contacted commercial laboratories that advertised TOF capability, and these laboratories indicated that they had not yet commercialized the TOF method (see Appendix 4 in ''Response to Comments on the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) Proposal,'' (USEPA, 2021i), which can be found in the electronic docket listed in the **ADDRESSES** section of this preamble). TOP has been more widely commercialized but is often used as an exploratory tool to estimate precursors.

In summary, there are still analytical challenges leading to uncertainties in the results using the TOF and TOP techniques. More research and method refinement are needed before a peer-reviewed validated method that meets UCMR quality control needs is available to address PFAS more broadly.

b. Legionella Pneumophila

Some comments supported EPA's proposal to not include *Legionella pneumophila* in UCMR 5, while others encouraged EPA to add it. EPA has decided not to include *Legionella pneumophila* in the final UCMR 5.

Under EPA's Surface Water Treatment Rule (SWTR), EPA established NPDWRs for *Giardia,* viruses, *Legionella,* turbidity and heterotrophic bacteria and set maximum contaminant level goals of zero for *Giardia lamblia,* viruses and *Legionella pneumophila* (54 FR 27486, June 29, 1989 (USEPA, 1989)). EPA is currently examining opportunities to enhance protection against *Legionella pneumophila* through revisions to the suite of Microbial and Disinfection Byproduct (MDBP) rules. In addition to the SWTR, the MDBP suite includes the Stage 1 and Stage 2 Disinfectants and Disinfection Byproduct Rules; the Interim Enhanced Surface Water Treatment Rule; and the Long Term 1 Enhanced Surface Water Treatment Rule.

As stated in the conclusions from EPA's third ''Six-Year Review of Drinking Water Standards'' (82 FR 3518, January 11, 2017 (USEPA, 2017)), ''EPA identified the following NPDWRs under the SWTR as candidates for revision, because of the opportunity to further reduce residual risk from pathogens (including opportunistic pathogens such as *Legionella*) beyond the risk addressed by the current SWTR.'' In accordance with the dates in the Settlement Agreement between EPA and Waterkeeper Alliance (*Waterkeeper Alliance, Inc.* v. *U.S. EPA,* No. 1:19–cv–00899–LJL (S.D.N.Y. Jun. 1, 2020)), the agency anticipates signing a proposal for revisions to the MDBP rules and a final action on the proposal by July 31, 2024 and September 30, 2027, respectively. EPA has concluded that UCMR 5 data collection for *Legionella pneumophila* would not be completed in time to meaningfully inform MDBP revision and that UCMR 5 data for *Legionella pneumophila* would soon lack significance because it would not reflect conditions in water systems after any regulatory revisions become effective (because water quality would be expected to change as a result of PWSs complying with such regulatory revisions).

EPA estimates that *Legionella pneumophila* monitoring under UCMR 5 would have added $10.5 million in new expenses for large PWSs, $20 million in new expenses for the agency for small system monitoring, and $0.5 million in new expenses for small PWSs and states over the 5-year UCMR period. Because the data would not be available in time to inform MDBP regulatory revisions and because MDBP revisions could change the presence of *Legionella pneumophila* in drinking water distribution systems (*Legionella* occurrence may change, for example, if the required minimum disinfectant residual concentration is higher following MDBP revisions), EPA concluded that the expense of this monitoring is not warranted given the limited utility of the data.

c. Haloacetonitriles

Some commenters agreed with EPA's rationale for not including the four unregulated haloacetonitrile disinfection byproducts (DBPs) in UCMR 5, while others encouraged EPA to include them. EPA has decided not to include haloacetonitrile DBPs in the final UCMR 5.

As was the case with *Legionella pneumophila,* EPA has concluded that UCMR 5 data collection for haloacetonitriles would not be completed in time to meaningfully inform MDBP revision and that UCMR 5 data would not reflect conditions in water systems after any regulatory revisions become effective (haloacetonitrile occurrence may change, for example, if the required minimum disinfectant residual concentration is higher following MDBP revisions).

As with *Legionella pneumophila,* inclusion of haloacetonitriles in UCMR 5 would introduce significant monitoring and reporting complexity and cost compared to the sampling design for PFAS and lithium. If haloacetonitriles were to be added to UCMR 5, most of the additional expenses would be borne by large PWSs (for analysis of their samples) and EPA (for analysis of samples from small PWSs). EPA estimates this would result in $13 million in new expenses for large PWSs, $19 million in new expenses for the agency, and $0.5 million in new expenses for small PWSs and states over the 5-year UCMR period.

Because the data would not be available in time to inform MDBP

regulatory revisions and because MDBP revisions could change the presence of haloacetonitriles in drinking water distribution systems, EPA concluded that the expense of this monitoring is not warranted given the limited utility of the data.

d. 1,2,3-Trichloropropane

EPA received some comments that support the agency's proposed decision to not include 1,2,3-trichloropropane (1,2,3-TCP) monitoring in UCMR 5, and others recommending that 1,2,3-TCP be included. EPA concluded that appropriate analytical methods are not currently available to support additional UCMR data collection (*i.e.,* above and beyond the data collection under UCMR 3 (USEPA, 2019c)).

Several commenters suggested that EPA consider analytical methods to monitor for 1,2,3-trichloropropane at lower levels. They suggested, for example, that the agency use California method SRL–524M (California DHS, 2002), which is prescribed by the state for compliance monitoring at 0.005 µg/L (5 ng/L). EPA has reviewed SRL 524M and determined that the associated quality control (QC) and IDC criteria do not meet the EPA's needs for drinking water analysis. See also EPA's ''Response to Comments on the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) Proposal,'' (USEPA, 2021i), which can be found in the electronic docket listed in the **ADDRESSES** section of this preamble.

Occurrence data collected during UCMR 3 (77 FR 26072, May 2, 2012 (USEPA, 2012)) for 1,2,3-trichloropropane may be found at *https://www.epa.gov/dwucmr/occurrence-data-unregulated-contaminant-monitoring-rule#3.*

B. What is the UCMR 5 sampling design?

1. This Final Rule

EPA has utilized up to three different tiers of contaminant monitoring, associated with three different ''lists'' of contaminants, in past UCMRs. EPA designed the monitoring tiers to reflect the availability and complexity of analytical methods, laboratory capacity, sampling frequency, and cost. The Assessment Monitoring tier is the largest in scope and is used to collect data to determine the national occurrence of ''List 1'' contaminants for the purpose of estimating national population exposure. Assessment Monitoring has been used in the four previous UCMRs to collect occurrence data from all systems serving more than 10,000 people and a representative sample of 800 smaller systems. Consistent with AWIA, the Assessment Monitoring approach was redesigned for UCMR 5 and reflects the plan, subject to additional appropriations being made available for this purpose, that would require all systems serving 3,300 or more people and a representative sample of systems serving 25 to 3,299 people to perform monitoring (USEPA, 2021a). The population-weighted sampling design for the nationally representative sample of small systems (used in previous UCMR cycles to select 800 systems serving 25 to 10,000 people and used in UCMR 5 to select 800 systems serving 25 to 3,299 people) calls for the sample to be stratified by water source type (ground water or surface water), service size category, and state (where each state is allocated a minimum of two systems in its State Monitoring Plan). The allowable margin of error at the 99 percent confidence level is ±1 percent for an expected contaminant occurrence of 1 percent at the national level. Assessment Monitoring is the primary tier used for contaminants and generally relies on analytical methods that use more common techniques that are expected to be widely available. EPA has used an Assessment Monitoring tier for 72 contaminants and contaminant groups over the course of UCMR 1 through UCMR 4. The agency is exclusively requiring Assessment Monitoring in UCMR 5. This monitoring approach yields the most complete set of occurrence data to support EPA's decision making.

2. Summary of Major Comments and EPA Responses

Many commenters expressed support for the increase in small system Assessment Monitoring, with no opposition to the inclusion of all PWSs serving 3,300 to 10,000 people in UCMR 5. The U.S. Small Business Administration asked that EPA clarify small-system responsibilities in the event of inadequate EPA funding to fully support the envisioned monitoring.

Recognizing the uncertainty in funding from year-to-year, the agency will implement a ''monitor if notified'' approach for PWSs serving 25 to 10,000 people. In 2022, EPA will notify the approximately 6,000 small PWSs tentatively selected for the expanded UCMR 5 (all PWSs serving 3,300 to 10,000 people and a statistically-based, nationally representative set of 800 PWSs serving 25 to 3,299 people) of their anticipated UCMR 5 monitoring requirements; that initial notification will specify that monitoring is conditioned on EPA having sufficient funds and will be confirmed in a second notification. Upon receiving appropriations for a particular year, EPA will determine the number of small PWSs whose monitoring is covered by the appropriations, and notify the included small PWSs of their upcoming requirements at least six months prior to their scheduled monitoring. EPA has made minor edits to 40 CFR 141.35 and 40 CFR 141.40 for consistency with this approach.

Additionally, to ensure that EPA has access to a nationally representative set of small-system data, even in the absence of sufficient appropriations to support the planned monitoring by small systems, a statistically-based nationally representative set of 800 PWSs will also be selected from among the PWSs serving 25 to 10,000 people. An updated description of the statistical approach for the nationally representative samples for UCMR 5 is available in the docket as ''Selection of Nationally Representative Public Water Systems for the Unregulated Contaminant Monitoring Rule: 2021 Update'' (USEPA 2021a).

To minimize the impact of the final rule on small systems (those serving 25 to 10,000 people), EPA pays for their sample kit preparation, sample shipping fees, and sample analysis. Large systems (those serving more than 10,000 people) pay for all costs associated with their monitoring. Exhibit 5 of this preamble shows a summary of the estimated number of PWSs subject to monitoring.

EXHIBIT 5—SYSTEMS EXPECTED TO PARTICIPATE IN UCMR 5 MONITORING

System size (number of people served)	National sample: Assessment monitoring design	Total number of systems per size category
	List 1 chemicals	
Small Systems[1] (25–3,299)	800 randomly selected systems (CWSs and NTNCWSs)	[4] 800
Small Systems[1 2] (3,300–10,000).	All systems (CWSs and NTNCWSs) subject to the availability of appropriations	[4] 5,147

EXHIBIT 5—SYSTEMS EXPECTED TO PARTICIPATE IN UCMR 5 MONITORING—Continued

System size (number of people served)	National sample: Assessment monitoring design	Total number of systems per size category
	List 1 chemicals	
Large Systems[3] (10,001 and over).	All systems (CWSs and NTNCWSs)	4,364
Total		10,311

[1] EPA pays for all analytical costs associated with monitoring at small systems.
[2] Counts for small PWSs serving 3,300–10,000 people are approximate.
[3] Large system counts are approximate.
[4] In the absence of appropriations to support monitoring at all PWSs serving 3,300 to 10,000 people, EPA could instead include as few as 400 PWSs serving 25 to 3,299 people and 400 PWSs serving 3,300 to 10,000 people (for a representative sample of 800 PWSs serving 25 to 10,000 people).

C. What is the sampling frequency and timing?

1. This Final Rule

This final rule maintains the proposed sampling frequency and timeframe for Assessment Monitoring. On a per-system basis, the anticipated number of samples collected by each system is consistent with sample collection during prior UCMR cycles (although, as described elsewhere in this document, the number of water systems expected to participate in UCMR 5 is significantly greater under this final rule per AWIA). Water systems will be required to collect samples based on the typical UCMR sampling frequency and timeframe as follows: For surface water, ground water under the direct influence of surface water, and mixed locations, sampling will take place for four consecutive quarters over the course of 12 months (total of 4 sampling events). Sampling events will occur three months apart. For example, if the first sample is taken in January, the second will then occur anytime in April, the third will occur anytime in July, and the fourth will occur anytime in October. For ground water locations, sampling will take place twice over the course of 12 months (total of 2 sampling events). Sampling events will occur five to seven months apart. For example, if the first sample is taken in April, the second sample will then occur anytime in September, October, or November.

EPA, in conjunction with the states, will initially determine schedules (year and months of monitoring) for large water systems. Thereafter, large PWSs will have an opportunity to modify this initial schedule for planning purposes or other reasons (*e.g.,* to spread costs over multiple years, if a sampling location will be closed during the scheduled month of monitoring, etc.). EPA will schedule and coordinate small system monitoring (for PWSs serving 3,300 to 10,000 people and for the nationally representative sample of smaller PWSs) by working closely with partnering states. State Monitoring Plans provide an opportunity for states to review and revise the initial sampling schedules developed by EPA (see discussion of State Monitoring Plans in Section III.D of this preamble).

2. Summary of Major Comments and EPA Responses

EPA received two comments recommending that the agency reduce the sampling frequency for both ground water (GW) and surface water (SW) systems, including a suggestion that UCMR 5 require only one sample per system. EPA concluded that less frequent data collection would affect the integrity of the data and result in insufficient data to fulfill the needs envisioned by the 1996 SDWA Amendments, particularly with regard to supporting the Administrator's regulatory determinations and drinking water regulation development. Maintaining the proposed sampling frequency allows the resulting contaminant data to be analyzed for temporal variability, in addition to between-system variability. These analyses are not possible with a single-sample structure. When making regulatory determinations, EPA evaluates the number of systems (and populations) with means or single measured values above health levels of concern, as both values provide important information.

EPA acknowledges that based on UCMR 3 (77 FR 26072, May 2, 2012 (USEPA, 2012)) data, the correlation between results from multiple sample events can be high; however, the approach suggested by commenters would yield less accurate data for several reasons. EPA's assessment of sampling frequency using UCMR 3 and UCMR 4 data (see Appendix 2 in ''Response to Comments on the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) Proposal,'' (USEPA, 2021i), which can be found in the electronic docket listed in the **ADDRESSES** section of this preamble) shows that for both SW and GW systems, there are numerous cases where occurrence is notably different between sample events. Focusing first on UCMR 3 results for PWS with SW sources, the number of sample points at which PFOS was measured at or above the MRL was 108 percent greater when considering multiple sample events, versus only considering the first sample event. There were multiple occasions where the results from the first sample event were below the health-based reference concentration while subsequent results were above it. Looking at UCMR 3 results for PWSs with GW sources, PFOS was measured at or above the MRL at 26 percent more sample points in the second sample event relative to the first. Similar to the UCMR 3 results for SW systems, there were multiple occasions where the second result from a GW system exceeded the reference concentration while the first result did not.

Some commenters suggested that between-system variability is much greater for PFAS than within-system variability. While it may be less than between-system variability, within-system variability can still be important. Shifting to a single sample prevents reasonable assessments of within-system variability and limits the ability to observe between-system variability estimates. This would then drastically reduce the ability to characterize uncertainty.

Additionally, although the provisions of AWIA could include the addition of approximately 5,200 more PWSs to UCMR 5 relative to earlier cycles and thus capture more spatial variation in the resulting dataset, it is important to note that spatial variation is different than temporal or seasonal variation. Capturing more of one does not diminish the influence of the others on national occurrence data and reducing the frequency of sampling eliminates

the possibility of analyzing the resulting data for temporal variation. In addition, statistical means based on two measurements have considerably less error than a single measurement per system, and provide a more robust dataset for future regulatory decisions. Having more than one sample event also greatly reduces the chance of underestimating the true proportion of occurrence of the contaminant in drinking water (*i.e.,* exposure).

Regarding monitoring frequency and burden, EPA notes that the agency allows large GW systems the opportunity to reduce monitoring burden by using approved representative entry points (40 CFR 141.35(c)(3)) as described in Section IV.D of this preamble. Representative monitoring plans will result in fewer samples and thus time and cost savings to the PWS. Consecutive systems with multiple connections from a particular wholesaler are also permitted to choose one entry point as representative, thus reducing burden.

D. Where are the sampling locations and what is representative monitoring?

1. This Final Rule

Consistent with past UCMR cycles, sample collection for UCMR 5 contaminants will take place at the entry point to the distribution system (EPTDS). As during past UCMRs and as described in 40 CFR 141.35(c)(3) of this preamble, this final rule will allow large ground water systems (or large surface water systems with ground water sources) that have multiple ground water EPTDSs to request approval to sample at representative monitoring locations rather than at each ground water EPTDS. GWRMPs approved under prior UCMRs may be used for UCMR 5, presuming no significant changes in the configuration of the ground water EPTDSs since the prior approval. Water systems that intend to use a previously approved plan must send EPA a copy of the approval documents received under prior UCMRs from their state (if reviewed by the state) or EPA.

Relative to the rules for prior UCMR cycles, this final rule provides greater flexibility to PWSs in submitting GWRMPs to EPA. Plans must be submitted to EPA six months prior to the PWS's scheduled sample collection, instead of by a specified date; those PWSs scheduled to collect samples in 2024 or 2025 will have significant additional time to develop and propose representative plans. PWSs, particularly those scheduled for sample collection in 2023, are encouraged to submit proposals for a new GWRMP by December 31, 2022, to allow time for review by EPA and, as appropriate, the state. EPA will work closely with the states to coordinate the review of GWRMPs in those cases where such review is part of the state's Partnership Agreement. Changes to inventory data in SDWARS that impact a PWS's representative plan before or during the UCMR sampling period must be reported within 30 days of the change. EPA will collaborate with small systems (particularly those with many ground water locations) to develop a GWRMP when warranted, recognizing that EPA pays for the analysis of samples from small systems.

2. Summary of Major Comments and EPA Responses

EPA received multiple comments regarding GWRMPs and representative sampling for wholesale systems and consecutive connections. Generally, commenters supported the continued use of GWRMPS and the use of previously approved monitoring plans. An additional supporting document, titled, ''Instructions for Preparing a Ground Water Representative Monitoring Plan for the Unregulated Contaminant Monitoring Rule,'' (USEPA, 2021j) has been placed in the electronic docket listed in the **ADDRESSES** section of this preamble.

Several commenters recommended that EPA not require monitoring by consecutive systems that purchase 100 percent of their water from wholesale systems that are already subject to UCMR 5 monitoring. They requested that EPA instead require wholesalers to identify the PWSIDs of consecutive systems receiving water from the wholesaler, and that EPA rely on wholesaler monitoring in lieu of monitoring by the consecutive systems. EPA has decided to require monitoring by consecutive systems to conduct monitoring in accordance with UCMR 5. Previous UCMR data demonstrate that wholesalers and purchasers can have different analytical results (see Appendix 3 in ''Response to Comments on the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) Proposal,'' (USEPA, 2021i), which can be found in the electronic docket listed in the **ADDRESSES** section of this preamble). For example, pairing the results from wholesaler to consecutive connections for 190 manganese results from UCMR 4 (81 FR 92666, December 20, 2016 (USEPA, 2016)), one-third of the results are higher at the wholesaler and one-third of the results are higher at the consecutive connection, with one-third of all results being comparable [±0.4 µg/L]. The agency therefore elected to maintain the proposed approach in which all eligible consecutive systems must monitor, irrespective of monitoring being conducted by the wholesale system from which they purchase drinking water.

E. How long do laboratories and PWSs have to report data?

1. This Final Rule

EPA is maintaining the revised reporting timeframes for laboratories and PWSs as proposed. For UCMR 5, laboratories have 90 days (versus 120 days in prior UCMR cycles) from the sample collection date to post and approve analytical results in SDWARS for PWS review. Large PWSs have 30 days (versus 60 days in prior UCMR cycles) to review and approve the analytical results posted to SDWARS. As with the UCMR 4 requirements, data will be considered approved and available for state and EPA review if the PWS takes no action within their allotted review period.

In the proposed rule for UCMR 5, EPA noted that multiple states have expressed an interest in earlier access to UCMR data (see Docket ID No. EPA–HQ–OW–2020–0530). EPA believes that the shorter timeframes for posting and approving data are feasible and reasonable based on our experience with UCMR reporting to date.

2. Summary of Major Comments and EPA Responses

Commenters generally agreed with the revised timeframes for laboratories to post and approve analytical results in SDWARS. The 90-day laboratory timeframe makes UCMR results more readily available to interested stakeholders and states. Some commenters supported the timely reporting of data by laboratories to ensure that PWSs have adequate time to reconcile QC issues, especially those that may require a PWS to resample. Some expressed concerns that the revised timeframe could be challenging for laboratories. Some suggested that the shorter timeframe be conditioned on consistent functionality and availability of SDWARS.

Commenters generally agreed with the changes in the timeframes for large PWSs to review and approve analytical results posted to SDWARS, though several requested that EPA maintain the 60-day review period.

EPA has observed that many laboratories are routinely posting data to SDWARS within 90 days of sample collection and that many large PWSs are approving and submitting data within 30 days of their laboratory posting the

data. Judging by reporting for 2020 monitoring under UCMR 4 (81 FR 92666, December 20, 2016 (USEPA, 2016)), more than 75 percent of laboratories posted and approved data within 90 days, and more than 85 percent of large PWSs who chose to act on their data, did so within 30 days of the laboratory posting it. During UCMR 3 and UCMR 4, less than half of large PWSs chose to actively review and approve their data, as opposed to letting the results default to ''approved'' status after the review period. The many large PWSs that have routinely chosen to not review and approve their data will not be impacted by the revised timeframe for PWS data review for UCMR 5. See also Appendix 5 in ''Response to Comments on the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) Proposal,'' (USEPA, 2021i), which can be found in the electronic docket listed in the **ADDRESSES** section of this preamble.

EPA does not anticipate functionality or availability issues with SDWARS during UCMR 5 but is prepared to make case-by-case exceptions for reporting timeframes should significant issues occur with the reporting system.

F. What are the reporting requirements for UCMR 5?

1. This Final Rule

Today's final rule removes 1 of the proposed data elements (''Direct Potable Reuse Water Information'') and maintains the 27 others described in the proposed rule. EPA has updated some of the data-element definitions for clarity and consistency in the reporting requirements. Please see Table 1 of 40 CFR 141.35(e) of this preamble for the complete list of data elements, definitions and drop-down options that will be provided in the data reporting system.

2. Summary of Major Comments and EPA Responses

a. Data Elements

EPA received multiple comments on the proposed contaminant-specific data elements, with some commenters questioning the quality, reliability, and utility of some of the data that would be provided to the agency per the proposed data element requirements. Several commenters requested that EPA include rationale explaining the intended use of such data. EPA has updated the data elements for clarity (*e.g.,* clarifying treatment types, and abbreviations for them; adding the treatment option ''NMT = not modified after testing'') and has provided additional rationale (including describing how the information could impact regulatory decision making and risk-management strategies) in the ''Response to Comments on the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) Proposal,'' (USEPA, 2021i), available in the UCMR 5 public docket (see the **ADDRESSES** section of this preamble). EPA acknowledges the data collected will have some limitations but believes that the collection of the information is still valuable. In addition, EPA notes the modest burden associated with the collection.

b. Reporting State Data

EPA received several comments suggesting that PWSs be permitted to submit occurrence data collected under state-based monitoring, in lieu of conducting UCMR 5 monitoring, to reduce the monitoring burden. In those cases where the monitoring required by a state is aligned with the requirements of UCMR 5, PWSs may be able to conduct PFAS monitoring that meets the needs of their state and UCMR 5, with the understanding that UCMR 5 requirements must be met. This includes the requirement that PFAS samples be analyzed by a UCMR 5-approved laboratory using EPA Method 533 and Method 537.1. EPA offers flexibility for PWSs to reschedule their UCMR 5 monitoring, and PWSs may do so to coordinate it with their state-required monitoring. PWSs wishing to conduct ''dual purpose'' monitoring (*i.e.,* concurrently meeting the state and UCMR 5 needs) may contact their state or EPA, as appropriate, if there are questions about whether the state and UCMR 5 requirements are being met.

G. What are the UCMR 5 Minimum Reporting Levels (MRLs) and how were they determined?

1. This Final Rule

EPA is maintaining the proposed minimum reporting levels for the UCMR 5 contaminants. EPA establishes MRLs to ensure consistency in the quality of the information reported to the agency. As defined in 40 CFR 141.40(a)(5)(iii) of this preamble, the MRL is the minimum quantitation level that, with 95 percent confidence, can be achieved by capable analysts at 75 percent or more of the laboratories using a specified analytical method. More detailed explanation of the MRL calculation is in the ''Technical Basis for the Lowest Concentration Minimum Reporting Level (LCMRL) Calculator'' (USEPA, 2010), available at (*https://www.epa.gov/dwanalyticalmethods/lowest-concentration-minimum-reporting-level-lcmrl-calculator*).

EPA requires each laboratory interested in supporting UCMR analyses to demonstrate that they can reliably make quality measurements at or below the established MRL to ensure that high quality results are being reported by participating laboratories. EPA established the proposed MRLs in 40 CFR 141.40(a)(3), Table 1 of this preamble, for each analyte/method by obtaining data from at least three laboratories that performed ''lowest concentration minimum reporting level'' (LCMRL) studies. The results from these laboratory LCMRL studies can be found in the ''UCMR 5 Laboratory Approval Manual'' (USEPA, 2021f), available in the electronic docket (see the **ADDRESSES** section of this preamble).

The multiple laboratory LCMRLs were then processed through a statistical routine to derive an MRL that, with 95 percent confidence, is predicted to be attainable by 75 percent of laboratories using the prescribed method. EPA considers these to be the lowest reporting levels that can practically and consistently be achieved on a national basis (recognizing that individual laboratories may be able to measure at lower levels).

2. Summary of Major Comments and EPA Responses

Some commenters recommended that EPA establish lower MRLs for the 29 PFAS in UCMR 5. MRLs used for the UCMR program are based on calculations that account for the ability of laboratories to report accurate and precise measurements with a specific statistical confidence. Based on the results from multiple laboratories that participated in MRL-setting studies, EPA concluded that the proposed MRLs represent the lowest feasible levels for a national MRL measure. Sensitivity (*i.e.,* quantitation limit) may improve with time, experience, and instrumentation advances.

H. What are the requirements for laboratory analysis of field reagent blank samples?

1. This Final Rule

EPA initially proposed that laboratories analyze all field reagent blank (FRB) samples, along with the corresponding field samples, to reduce the possibility of invalidating a positive field sample result (*i.e.,* a field sample result at or above the MRL) because of FRB hold times being exceeded.

2. Summary of Major Comments and EPA Responses

EPA did not receive any comments expressing concerns with the laboratory approval process; however, the agency did receive a comment on the FRB sample analysis criteria, suggesting that the agency not require analysis of every FRB sample. EPA Method 537.1 and Method 533, used for PFAS analysis, require collection of a corresponding FRB sample from each unique sampling location for each sampling event. The methods require that the FRB be analyzed if there is a positive result for a PFAS analyte in a corresponding field sample. Based on further consideration, EPA is now providing laboratories with discretion as to whether they analyze every FRB sample proactively or only those associated with positive field sample results. This is with the understanding that laboratories must analyze field samples promptly enough such that the corresponding FRB analyses, if needed, may be completed within the prescribed hold time. Compliance with the method hold-time requirements, and other provisions of the methods, is a condition of maintaining laboratory approval. EPA is studying the possibility of extending the FRB hold times for EPA Method 537.1 and Method 533, and will communicate the results of the studies with the approved laboratories.

I. How will EPA support risk communication for UCMR 5 results?

EPA received comments requesting that the agency develop and provide risk communication materials to support interpretation and characterization of UCMR 5 results. EPA intends to publish a ''reference concentration'' summary document with available EPA health values; provide a template for PWSs to consider using in communicating with their customers about the detection of PFAS in drinking water; and provide other supporting material as risk-related information becomes available.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket. A full analysis of potential costs associated with this action, the ''Information Collection Request for the Final Unregulated Contaminant Monitoring Rule (UCMR 5),'' (USEPA, 2021b) ICR Number 2040–0304, is also available in the docket (Docket ID No. EPA–HQ–OW–2020–0530). A summary of the ICR can be found in Section I.C of this preamble.

B. Paperwork Reduction Act (PRA)

The information collection activities in this final rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document (USEPA, 2021b) that EPA prepared has been assigned EPA ICR number ICR 2683.02. You can find a copy of the ICR in the docket for this final rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The information that EPA will collect under this final rule fulfills the statutory requirements of Section1445(a)(2) of SDWA, as amended in 1996, 2018, and 2019. The data will describe the source of the water, location, and test results for samples taken from public water systems (PWSs) as described in 40 CFR 141.35(e). The information collected will support EPA's decisions as to whether or not to regulate particular contaminants under SDWA. Reporting is mandatory. The data are not subject to confidentiality protection.

The 5-year UCMR 5 period spans 2022–2026. UCMR 5 sample collection begins in 2023 and continues through 2025. Since ICRs cannot be approved by OMB for a period longer than three years pursuant to 5 CFR 1320.10, the primary analysis in the ICR only covers the first three years of the UCMR 5 period (*i.e.,* 2022–2024). Prior to expiration of the initial UCMR 5 ICR, EPA will seek to extend the ICR and thus receive approval to collect information under the PRA in the remaining two years of the UCMR 5 period (2025–2026).

EPA received several comments regarding cost and burden of the proposed rule. Those comments recommended that EPA provide more accurate cost estimates. EPA's response is detailed more fully in the ''Response to Comments on the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) Proposal,'' (USEPA, 2021i), which can be found in the electronic docket listed in the **ADDRESSES** section of this preamble.

EPA has reviewed and, as appropriate, revised the cost and burden figures for UCMR 5; this includes using updated unit cost estimates for sample analysis. The annual burden and cost estimates described in this section are based on the implementation assumptions described in Section III of this preamble, among them the inclusion of all systems serving 3,300 to 10,000 people and a representative sample of smaller systems. As such, those estimates represent an upper bound. If EPA does not receive the necessary appropriations in one or more of the collections years—and thus collects data from fewer small systems—the actual costs would be lower than those estimated here. In general, burden hours were calculated by:

1. Determining the activities that PWSs and states would complete to comply with UCMR activity;
2. Estimating the number of hours per activity;
3. Estimating the number of respondents per activity; and
4. Multiplying the hours per activity by the number of respondents for that activity.

Respondents/affected entities: The respondents/affected entities are small PWSs (those serving 25 to 10,000 people); large PWSs (those serving 10,001 to 100,000 people); very large PWSs (those serving more than 100,000 people); and states.

Respondent's obligation to respond: Mandatory (40 CFR 141.35).

Estimated number of respondents: Respondents to UCMR 5 include 5,947 small PWSs, 4,364 large PWSs, and the 56 primacy agencies (50 States, one Tribal nation, and five Territories) for a total of 10,367 respondents.

Frequency of response: The frequency of response varies across respondents and years. Across the initial 3-year ICR period for UCMR 5, small PWSs will sample an average of 2.8 times per PWS (*i.e.,* number of responses per PWS); large PWSs will sample and report an average of 3.2 times per PWS; and very large PWSs will sample and report an average of 3.7 times per PWS.

Total estimated burden: 48,469 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $9,404,007 annualized capital or operation & maintenance costs.

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 OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the agency will

announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

For purposes of assessing the impacts of this final rule on small entities, EPA considered small entities to be PWSs serving 25 to 10,000 people. As required by the RFA, EPA proposed using this alternative definition in the **Federal Register** (63 FR 7606, February 13, 1998 (USEPA, 1998a)), sought public comment, consulted with the Small Business Administration (SBA) Office of Advocacy, and finalized the alternative definition in the Consumer Confidence Reports rulemaking (63 FR 44512, August 19, 1998 (USEPA, 1998b)). As stated in that document, the alternative definition applies to this regulation.

EXHIBIT 6—NUMBER OF PUBLICLY- AND PRIVATELY-OWNED SMALL SYSTEMS SUBJECT TO UCMR 5 [1]

System size (number of people served)	Publicly-owned	Privately-owned	Total [2]
Ground Water			
500 and under	42	126	168
501 to 3,300	320	121	441
3,301 to 10,000	2,334	541	2,875
Subtotal Ground Water	2,696	788	3,484
Surface Water (and Ground Water Under the Direct Influence of Surface Water)			
500 and under	9	11	20
501 to 3,300	126	45	171
3,301 to 10,000	1,762	510	2,272
Subtotal Surface Water	1,897	566	2,463
Total of Small Water Systems	4,593	1,354	5,947

[1] In the absence of appropriations to support monitoring at all PWSs serving 3,300 to 10,000 people, EPA could instead include as few as 400 PWSs serving 25 to 3,299 people and 400 PWSs serving 3,300 to 10,000 people (for a representative sample of 800 PWSs serving 25 to 10,000 people).
[2] PWS counts were adjusted to display as whole numbers in each size category.

The basis for the UCMR 5 RFA certification is as follows: For the 5,947 small water systems that EPA anticipates will be affected, per the planned monitoring, the average annual cost for complying with this final rule represents an average of 0.02 percent of system revenues. The average yearly cost to small systems to comply with UCMR 5 over the 5-year period of 2022–2026, is approximately $0.3 million.

EPA anticipates that approximately one third of the 5,947 small PWSs will collect samples in each of three years (2023, 2024, and 2025).

PWS costs are attributed to the labor required for reading about UCMR 5 requirements, monitoring, reporting, and record keeping. The estimated average annual burden across the 5-year UCMR 5 implementation period of 2022–2026 is 1.3 hours at $52 per small system. By assuming all costs for laboratory analyses, shipping and quality control for small entities, EPA incurs the entirety of the non-labor costs associated with UCMR 5 small system monitoring, or 96 percent of total small system testing costs. Exhibit 7 and Exhibit 8 of this preamble present the estimated economic impacts in the form of a revenue test for publicly- and privately-owned systems.

EXHIBIT 7—UCMR 5 RELATIVE COST ANALYSIS FOR SMALL PUBLICLY-OWNED SYSTEMS

[2022–2026] [1]

System size (number of people served)	Annual number of systems impacted [2]	Average annual hours per system	Average annual cost per system	SBREFA criteria-revenue test [3] (%)
Ground Water Systems				
500 and under	8	1.0	$40.65	0.09
501 to 3,300	64	1.1	43.37	0.02
3,301 to 10,000	467	1.3	49.92	0.01
Surface Water (and Ground Water Under the Direct Influence of Surface Water) Systems				
500 and under	2	1.4	54.39	0.07
501 to 3,300	25	1.4	56.19	0.02
3,301 to 10,000	353	1.5	57.39	0.004

[1] In the absence of appropriations to support monitoring at all PWSs serving 3,300 to 10,000 people, EPA could instead include as few as 400 PWSs serving 25 to 3,299 people and 400 PWSs serving 3,300 to 10,000 people (for a representative sample of 800 PWSs serving 25 to 10,000 people).

[2] PWS counts were adjusted to display as whole numbers in each size category. Includes the publicly-owned portion of small systems subject to UCMR 5.
[3] Costs are presented as a percentage of median annual revenue for each size category.

EXHIBIT 8—UCMR 5 RELATIVE COST ANALYSIS FOR SMALL PRIVATELY-OWNED SYSTEMS
[2022–2026] [1]

System size (number of people served)	Annual number of systems impacted [2]	Average annual hours per system	Average annual cost per system	SBREFA criteria-revenue test [3] (%)
Ground Water Systems				
500 and under	25	1.0	$40.65	0.48
501 to 3,300	24	1.1	$43.37	0.03
3,301 to 10,000	108	1.3	$49.92	0.004
Surface Water (and Ground Water Under the Direct Influence of Surface Water) Systems				
500 and under	2	1.4	$54.39	0.11
501 to 3,300	9	1.4	$56.19	0.02
3,301 to 10,000	102	1.5	$57.39	0.004

[1] In the absence of appropriations to support monitoring at all PWSs serving 3,300 to 10,000 people, EPA could instead include as few as 400 PWSs serving 25 to 3,299 people and 400 PWSs serving 3,300 to 10,000 people (for a representative sample of 800 PWSs serving 25 to 10,000 people).
[2] PWS counts were adjusted to display as whole numbers in each size category. Includes the privately-owned portion of small systems subject to UCMR 5.
[3] Costs are presented as a percentage of median annual revenue for each size category.

Up to 9.4 percent of all small systems (*i.e.,* up to 5,947 small PWSs serving 25 to 10,000 people) will participate in UCMR 5 if EPA receives the necessary appropriations to support its plan. EPA has determined that participating small systems will experience an average impact of 0.02 percent of revenues. This accounts for small PWSs familiarizing themselves with the regulatory requirements; reading sampling instructions; traveling to the sampling location; collecting and shipping the samples; and maintaining their records. The 5,947 small PWSs are comprised of all 5,147 systems serving between 3,300 and 10,000 people, and the representative group of 800 systems serving between 25 and 3,299 people; the remainder of small systems will not participate in UCMR 5 monitoring and will not be impacted.

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action along with a description of the very minor impacts are previously addressed in this section. Although this final rule will not have a significant economic impact on a substantial number of small entities, EPA has attempted to reduce impacts by assuming all costs for analyses of the samples, and for shipping the samples from small systems to laboratories contracted by EPA to analyze the UCMR 5 samples (the cost of shipping is included in the cost of each analytical method). EPA has historically set aside $2.0 million each year from the Drinking Water State Revolving Fund (DWSRF) with its authority to use DWSRF monies for the purposes of implementing this provision of SDWA. EPA anticipates drawing on these and additional funds, if available, to implement the plan and carry out the expanded UCMR monitoring approach outlined in AWIA. We have therefore concluded that this action will have no significant impact on any directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action implements mandate(s) specifically and explicitly set forth in SDWA Section 1445(a)(2), Monitoring Program for Unregulated Contaminants.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not 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.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action has Tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized Tribal governments, nor preempt Tribal law. As described previously in this document, this final rule requires monitoring by all large PWSs. Information in the SDWIS/Fed water system inventory indicates there are approximately 27 large Tribal PWSs (serving 10,001 to 40,000 people). EPA estimates the average annual cost to each of these large PWSs, over the 5-year rule period, to be $1,783. This cost is based on a labor component (associated with the collection of samples), and a non-labor component (associated with shipping and laboratory fees). As planned, UCMR 5 is expected to also require monitoring by all small PWSs serving 3,300 to 10,000 people and a nationally representative sample of small PWSs serving 25 to 3,299 people. Information in the SDWIS/Fed water system inventory indicates there are approximately 75 small Tribal PWSs (serving 3,300 to 10,000 people). EPA estimates that less than 2 percent of small Tribal systems serving 25 to 3,299 people will be selected as part of the nationally representative sample. EPA estimates the average annual cost to small Tribal systems over the 5-year rule period to be $52. Such cost is based on the labor associated with collecting a sample and

preparing it for shipping. All other small-PWS expenses (associated with shipping and laboratory fees) are paid by EPA.

EPA consulted with Tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to permit them to have meaningful and timely input into its development. A summary of that consultation, titled, ''Summary of the Tribal Coordination and Consultation Process for the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) Proposal,'' is provided in the electronic docket listed in the **ADDRESSES** section of this preamble.

As required by section 7(a), the EPA's Tribal Consultation Official has certified that the requirements of the executive order have been met in a meaningful and timely manner. A copy of the certification is included in the docket for this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern such an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy and has not otherwise been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. This is a national drinking water occurrence study that was submitted to OMB for review.

I. National Technology Transfer and Advancement Act (NTTAA)

This action involves technical standards. EPA has identified options that involve using analytical methods developed by the agency and three major voluntary consensus method organizations to support UCMR 5 monitoring. The voluntary consensus method organizations are Standard Methods for the Examination of Water and Wastewater, and ASTM International. EPA identified acceptable consensus method organization standards for the analysis of lithium. A summary of each method along with how the method specifically applies to UCMR 5 can be found in Section III.I of this preamble.

All of these standards are reasonably available for public use. EPA methods are free for download on the agency's website. The methods in the Standard Methods for the Examination of Water and Wastewater 23rd edition are consensus standards, available for purchase from the publisher, and are commonly used by the drinking water laboratory community. The methods in the Standard Methods Online are consensus standards, available for purchase from the publisher's website, and are commonly used by the drinking water laboratory community. The methods from ASTM International are consensus standards, are available for purchase from the publisher's website, and are commonly used by the drinking water laboratory community.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. Background information regarding EPA's consideration of Executive Order 12898 in the development of this final rule is provided in Section III.F of this preamble, and an additional supporting document, titled, ''Summary of Environmental Justice Considerations for the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) Proposal,'' has been placed in the electronic docket listed in the **ADDRESSES** section of this preamble.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and 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).

VI. References

(i) ASDWA. 2013. *Insufficient Resources for State Drinking Water Programs Threaten Public Health: An Analysis of State Drinking Water Programs' Resources and Needs.* December 2013. Available at *https://www.asdwa.org/asdwa-reports/.*

(ii) ASTM. 2020. ASTM D1976–20—*Standard Test Method for Elements in Water by Inductively-Coupled Plasma Atomic Emission Spectroscopy.* ASTM, 100 Barr Harbor Drive, West Conshohocken, PA, 19428. Approved May 1, 2020. Available for purchase at *https://www.astm.org/Standards/D1976.htm.*

(iii) California DHS. 2002. California Department of Health Services. *Determination of 1,2,3-Trichloropropane in Drinking Water by Purge and Trap Gas Chromatography/Mass Spectrometry.* Division of Drinking Water and Environmental Management, Sanitation and Radiation Laboratories Branch, Berkeley, CA. Available at *https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/123-tcp/tcp_by_pt_gcms.pdf.*

(iv) Settlement Agreement, *Waterkeeper Alliance, Inc.* v. *U.S. EPA,* No. 1:19–cv–00899–LJL (S.D.N.Y. Jun. 1, 2020).

(v) SM. 2017. 3120B—Metals by Plasma Emission Spectroscopy (2017): Inductively Coupled Plasma (ICP) Method. *Standard Methods for the Examination of Water and Wastewater, 23rd edition.* American Public Health Association, 800 I Street NW, Washington, DC 20001–3710.

(vi) SM Online. 1999. 3120B–99—Metals by Plasma Emission Spectroscopy: Inductively Coupled Plasma (ICP) Method (Editorial Revisions, 2020). *Standard Methods Online.* Available for purchase at *http://www.standardmethods.org.*

(vii) USEPA. 1989. *National Primary Drinking Water Regulations; Filtration, Disinfection; Turbidity, Giardia lamblia, Viruses, Legionella, and Heterotrophic Bacteria; Final Rule.* **Federal Register**. Vol. 54, No. 124, p. 27486, June 29, 1989.

(viii) USEPA. 1994. *EPA Method 200.7—Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,* Revision 4.4. Office of Research and Development, Cincinnati, OH. Available at *https://www.epa.gov/esam/method-2007-determination-metals-and-trace-elements-water-and-wastes-inductively-coupled-plasma.*

(ix) USEPA. 1998a. National Primary Drinking Water Regulations: Consumer Confidence Reports; Proposed Rule. **Federal Register**. Vol. 63, No. 30, p. 7606, February 13, 1998.

(x) USEPA. 1998b. National Primary Drinking Water Regulation: Consumer Confidence Reports; Final Rule. **Federal Register**. Vol. 63, No. 160, p. 44512, August 19, 1998.

(xi) USEPA. 2010. *Technical Basis for the Lowest Concentration Minimum Reporting Level (LCMRL) Calculator.* EPA 815–R–11–001. Office of Water. December 2010. Available at *https://www.epa.gov/dwanalyticalmethods.*

(xii) USEPA. 2011. *Exposure Factors Handbook 2011 Edition (Final Report).* U.S. EPA, Washington, DC, EPA/600/R–09/052F. Office of Research and Development, Washington, DC. September 2011. Available at *https://www.epa.gov/expobox/about-exposure-factors-handbook.*

(xiii) USEPA. 2012. Revisions to the Unregulated Contaminant Monitoring Regulation (UCMR 3) for Public Water Systems; Final Rule. **Federal Register**. Vol. 77, No. 85, p. 26072, May 2, 2012.
(xiv) USEPA. 2016. Revisions to the Unregulated Contaminant Monitoring Rule (UCMR 4) for Public Water Systems and Announcement of Public Meeting. **Federal Register**. Vol. 81, No. 244, p. 92666, December 20, 2016.
(xv) USEPA. 2017. National Primary Drinking Water Regulations; Announcement of the Results of EPA's Review of Existing Drinking Water Standards and Request for Public Comment and/or Information on Related Issues. **Federal Register**. Vol. 82, No. 7, p. 3518, January 11, 2017.
(xvi) USEPA. 2018. *Method Development for Unregulated Contaminants in Drinking Water: Public Meeting and Webinar.* EPA 815–A–18–001. Office of Water. June 2018. Available at *https://www.epa.gov/dwanalyticalmethods.*
(xvii) USEPA. 2019a. *Development of the Proposed Unregulated Contaminant Monitoring Rule for the Fifth Monitoring Cycle (UCMR 5).* Presentation Slides. EPA 815–A–19–001. Office of Water. Available at *https://www.epa.gov/dwucmr/unregulated-contaminant-monitoring-rule-ucmr-meetings-and-materials.*
(xviii) USEPA. 2019b. *EPA Method 533—Determination of Per- and Polyfluoroalkyl Substances in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry.* EPA 815–B–19–020. Office of Water, Cincinnati, OH. November 2019. Available at *https://www.epa.gov/dwanalyticalmethods.*
(xix) USEPA. 2019c. Appendix C: 1,2,3-Trichloropropane in *Regulatory Determination 4 Support Document for Selected Contaminants from the Fourth Drinking Water Contaminant Candidate List (CCL 4).* EPA 815–R–19–006. Docket ID EPA–HQ–OW–2019–0583. Available at *https://www.regulations.gov.*
(xx) USEPA. 2020. *EPA Method 537.1—Determination of Selected Per- and Polyfluorinated Alkyl Substances in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS).* Version 2.0. EPA/600/R–20/006. Office of Research and Development, Cincinnati, OH. March 2020. Available at *https://www.epa.gov/dwanalytical methods.*
(xxii) USEPA. 2021a. *Selection of Nationally Representative Public Water Systems for the Unregulated Contaminant Monitoring Rule: 2021 Update.* EPA 815–B–21–012. Office of Water. December 2021.
(xxiii) USEPA. 2021b. *Information Collection Request for the Final Unregulated Contaminant Monitoring Rule (UCMR 5).* EPA 815–B–21–008. Office of Water. December 2021.
(xxiv) USEPA. 2021c. *Revisions to the Unregulated Contaminant Monitoring Rule for the Fifth Monitoring Cycle (UCMR 5): Public Meeting and Webinar.* Presentation Slides. EPA 815–A–21–001. Office of Water. April 2021. Available at *https://www.epa.gov/dwucmr/unregulated-contaminant-monitoring-rule-ucmr-meetings-and-materials.*
(xxv) USEPA. 2021d. Drinking Water Contaminant Candidate List 5—Draft. **Federal Register**. Vol. 86, No. 135 p. 37948, July 19, 2021.
(xxvi) USEPA. 2021e. *Information Compendium for Contaminants for the Final Unregulated Contaminant Monitoring Rule (UCMR 5).* EPA 815–B–21–009. Office of Water. December 2021.
(xxvii) USEPA. 2021f. *UCMR 5 Laboratory Approval Manual.* EPA 815–B–21–010. Office of Water. December 2021.
(xxviii) USEPA. 2021g. Revisions to the Unregulated Contaminant Monitoring Rule for Public Water Systems and Announcement of Public Meeting; Proposed Rule and Notice of Public Meeting. **Federal Register**. Vol. 86, No. 46, p. 13846, March 11, 2021.
(xxix) USEPA. 2021h. *Revisions to 40 CFR 141.35 and 141.40.* EPA 815–B–21–011. Office of Water. December 2021. Available in EPA's public docket (under Docket ID No. EPA–HQ–OW–2020–0530) at *https://www.regulations.gov.*
(xxx) USEPA. 2021i. *Response to Comments on the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) Proposal.* EPA 815–R–21–008. Office of Water. December 2021.
(xxi) USEPA. 2021j. *Instructions for Preparing a Ground Water Representative Monitoring Plan for the Unregulated Contaminant Monitoring Rule.* EPA 815–B–21–013. Office of Water. December 2021.

List of Subjects in 40 CFR Part 141

Environmental protection, Chemicals, Incorporation by reference, Indian—lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water supply.

Michael S. Regan,

Administrator.

For the reasons set forth in the preamble, EPA amends 40 CFR part 141 as follows:

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

■ 1. The authority citation for part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

Subpart D—Reporting and Recordkeeping

■ 2. Amend § 141.35 as follows:
■ a. In paragraph (a), revise the fourth sentence;
■ b. In paragraph (c)(1), remove the text ''December 31, 2017'' and add, in its place the text ''December 31, 2022'';
■ c. Revise paragraphs (c)(2), (c)(3)(i) through (iii), (c)(4), (c)(5)(i), and (c)(6)(ii);
■ d. In paragraph (d)(2), revise the first, second, and third sentences; and
■ f. Revise paragraph (e).

The revisions read as follows:

§ 141.35 Reporting for unregulated contaminant monitoring results.

(a) * * * For the purposes of this section, PWS ''population served'' is the retail population served directly by the PWS as reported to the Federal Safe Drinking Water Information System (SDWIS/Fed). * * *

* * * * *

(c) * * *

(2) *Sampling location inventory information.* You must provide your inventory information by December 31, 2022, using EPA's electronic data reporting system, as specified in paragraph (b)(1) of this section. You must submit, verify, or update data elements 1–9 (as defined in Table 1 of paragraph (e) of this section) for each sampling location, or for each approved representative sampling location (as specified in paragraph (c)(3) of this section) regarding representative sampling locations. If this information changes, you must report updates, including new sources, and sampling locations that are put in use before or during the UCMR sampling period, to EPA's electronic data reporting system within 30 days of the change.

(3) * * *

(i) *Qualifications.* Large PWSs that have EPA- or State-approved representative EPTDS sampling locations from a previous UCMR cycle, or as provided for under 40 CFR 141.23(a)(1), 40 CFR 141.24(f)(1), or 40 CFR 141.24(h)(1), may submit a copy of documentation from your State or EPA that approves your representative sampling plan. PWSs that do not have an approved representative EPTDS sampling plan may submit a proposal to sample at representative EPTDS(s) rather than at each individual EPTDS if: You use ground water as a source; all of your well sources have either the same treatment or no treatment; and you have multiple EPTDSs from the same source (*i.e.,* same aquifer). You must submit a copy of the existing or proposed representative EPTDS sampling plan, as appropriate, at least six months prior to your scheduled sample collection, as specified in paragraph (b)(1) of this section. If changes to your inventory that impact your representative plan occur before or during the UCMR sampling period, you must report updates within 30 days of the change.

(ii) *Demonstration.* If you are submitting a proposal to sample at representative EPTDS(s) rather than at each individual EPTDS, you must demonstrate that any EPTDS that you propose as representative of multiple wells is associated with a well that draws from the same aquifer as the wells it will represent. The proposed well must be representative of the highest annual volume and most consistently active wells in the representative array. If that representative well is not in use at the scheduled sampling time, you must select and sample an alternative representative well. You must submit the information defined in Table 1, paragraph (e) of this section for each proposed representative sampling location. You must also include documentation to support your proposal that the specified wells are representative of other wells. This documentation can include system-maintained well logs or construction drawings indicating that the representative well(s) is/are at a representative depth, and details of well casings and grouting; data demonstrating relative homogeneity of water quality constituents (*e.g.,* pH, dissolved oxygen, conductivity, iron, manganese) in samples drawn from each well; and data showing that your wells are located in a limited geographic area (*e.g.,* all wells within a 0.5 mile radius) and/or, if available, the hydrogeologic data indicating the ground water travel time between the representative well and each of the individual wells it represents (*e.g.,* all wells within a five-year time of travel delineation). Your proposal must be sent in writing to EPA, as specified in paragraph (b)(1) of this section.

(iii) *Approval.* EPA or the State (as specified in the Partnership Agreement reached between the State and EPA) will review your proposal and coordinate any necessary changes with you. Your plan will not be final until you receive written approval from EPA, identifying the final list of EPTDSs where you will be required to monitor.

(4) *Contacting EPA if your PWS has not been notified of requirements.* If you believe you are subject to UCMR requirements, as defined in 40 CFR 141.40(a)(1) and (a)(2)(i), and you have not been contacted by either EPA or your State by April 26, 2022, you must send a letter to EPA, as specified in paragraph (b)(1) of this section. The letter must be from your PWS Official and must include an explanation as to why the UCMR requirements are applicable to your system along with the appropriate contact information. A copy of the letter must also be submitted to the State as directed by the State. EPA will make an applicability determination based on your letter, and in consultation with the State when necessary and will notify you regarding your applicability status and required sampling schedule. However, if your PWS meets the applicability criteria specified in 40 CFR 141.40(a)(2)(i), you are subject to the UCMR monitoring and reporting requirements, regardless of whether you have been contacted by the State or EPA.

(5) * * *

(i) *General rescheduling notification requirements.* Large systems may independently change their monitoring schedules up to December 31, 2022, using EPA's electronic data reporting system, as specified in paragraph (b)(1) of this section. After this date has passed, if your PWS cannot sample according to your assigned sampling schedule (*e.g.,* because of budget constraints, or if a sampling location will be closed during the scheduled month of monitoring), you must mail or email a letter to EPA, as specified in paragraph (b)(1) of this section, prior to the scheduled sampling date. You must include an explanation of why the samples cannot be taken according to the assigned schedule, and you must provide the alternative schedule you are requesting. You must not reschedule monitoring specifically to avoid sample collection during a suspected vulnerable period. You are subject to your assigned UCMR sampling schedule or the schedule that you revised on or before December 31, 2022, unless and until you receive a letter from EPA specifying a new schedule.

* * * * *

(6) * * *

(ii) *Reporting schedule.* You must require your laboratory, on your behalf, to post and approve the data in EPA's electronic data reporting system, accessible at *https://www.epa.gov/dwucmr,* for your review within 90 days from the sample collection date (sample collection must occur as specified in 40 CFR 141.40(a)(4)). You then have 30 days from when the laboratory posts and approves your data to review, approve, and submit the data to the State and EPA via the agency's electronic data reporting system. If you do not electronically approve and submit the laboratory data to EPA within 30 days of the laboratory posting approved data, the data will be considered approved by you and available for State and EPA review.

* * * * *

(d) * * *

(2) *Sampling location inventory information.* You must provide your inventory information by December 31, 2022, using EPA's electronic data reporting system, as specified in paragraph (b)(1) of this section. If this information changes, you must report updates, including new sources, and sampling locations that are put in use before or during the UCMR sampling period, to EPA's electronic data reporting system within 30 days of the change, as specified in paragraph (b)(1) of this section. * * *

(e) *Data elements.* Table 1 defines the data elements that must be provided for UCMR monitoring.

TABLE 1 TO PARAGRAPH (e)—UNREGULATED CONTAMINANT MONITORING REPORTING REQUIREMENTS

Data element	Definition
1. Public Water System Identification (PWSID) Code.	The code used to identify each PWS. The code begins with the standard 2-character postal State abbreviation or Region code; the remaining 7 numbers are unique to each PWS in the State. The same identification code must be used to represent the PWS identification for all current and future UCMR monitoring.
2. Public Water System Name	Unique name, assigned once by the PWS.
3. Public Water System Facility Identification Code.	An identification code established by the State or, at the State's discretion, by the PWS, following the format of a 5-digit number unique within each PWS for each applicable facility (i.e., for each source of water, treatment plant, distribution system, or any other facility associated with water treatment or delivery). The same identification code must be used to represent the facility for all current and future UCMR monitoring.
4. Public Water System Facility Name.	Unique name, assigned once by the PWS, for every facility ID (*e.g.,* Treatment Plant).

TABLE 1 TO PARAGRAPH (e)—UNREGULATED CONTAMINANT MONITORING REPORTING REQUIREMENTS—Continued

Data element	Definition
5. Public Water System Facility Type.	That code that identifies that type of facility as either: CC = Consecutive connection. SS = Sampling station. TP = Treatment plant. OT = Other.
6. Water Source Type	The type of source water that supplies a water system facility. Systems must report one of the following codes for each sampling location: SW = Surface water (to be reported for water facilities that are served entirely by a surface water source during the 12-month period). GU = Ground water under the direct influence of surface water (to be reported for water facilities that are served all or in part by ground water under the direct influence of surface water at any time during the 12-month sampling period), and are not served at all by surface water during this period. MX = Mixed water (to be reported for water facilities that are served by a mix of surface water, ground water, and/or ground water under the direct influence of surface water during the 12-month period). GW = Ground water (to be reported for water facilities that are served entirely by a ground water source during the 12-month period).
7. Sampling Point Identification Code.	An identification code established by the State, or at the State's discretion, by the PWS, that uniquely identifies each sampling point. Each sampling code must be unique within each applicable facility, for each applicable sampling location (i.e., entry point to the distribution system). The same identification code must be used to represent the sampling location for all current and future UCMR monitoring.
8. Sampling Point Name	Unique sample point name, assigned once by the PWS, for every sample point ID (*e.g.,* Entry Point).
9. Sampling Point Type Code	A code that identifies the location of the sampling point as: EP = Entry point to the distribution system.
10. Disinfectant Type	All of the disinfectants/oxidants that have been added prior to and at the entry point to the distribution system. Please select all that apply: PEMB = Permanganate. HPXB = Hydrogen peroxide. CLGA = Gaseous chlorine. CLOF = Offsite generated hypochlorite (stored as a liquid form). CLON = Onsite generated hypochlorite. CAGC = Chloramine (formed with gaseous chlorine). CAOF = Chloramine (formed with offsite hypochlorite). CAON = Chloramine (formed with onsite hypochlorite). CLDB = Chlorine dioxide. OZON = Ozone. ULVL = Ultraviolet light. OTHD = All other types of disinfectant/oxidant. NODU = No disinfectant/oxidant used.
11. Treatment Information	Treatment information associated with the sample point. Please select all that apply. CON = Conventional (non-softening, consisting of at least coagulation/sedimentation basins and filtration). SFN = Softening. RBF = River bank filtration. PSD = Pre-sedimentation. INF = In-line filtration. DFL = Direct filtration. SSF = Slow sand filtration. BIO = Biological filtration (operated with an intention of maintaining biological activity within filter). UTR = Unfiltered treatment for surface water source. GWD = Groundwater system with disinfection only. PAC = Application of powder activated carbon. GAC = Granular activated carbon adsorption (not part of filters in CON, SFN, INF, DFL, or SSF). AIR = Air stripping (packed towers, diffused gas contactors). POB = Pre-oxidation with chlorine (applied before coagulation for CON or SFN plants or before filtration for other filtration plants). MFL = Membrane filtration. IEX = Ionic exchange. DAF = Dissolved air floatation. CWL = Clear well/finished water storage without aeration. CWA = Clear well/finished water storage with aeration. ADS = Aeration in distribution system (localized treatment). OTH = All other types of treatment. NTU = No treatment used. DKN = Do not know.
12. Sample Collection Date	The date the sample is collected, reported as 4-digit year, 2-digit month, and 2-digit day (YYYYMMDD).
13. Sample Identification Code	An alphanumeric value up to 30 characters assigned by the laboratory to uniquely identify containers, or groups of containers, containing water samples collected at the same sampling location for the same sampling date.
14. Contaminant	The unregulated contaminant for which the sample is being analyzed.
15. Analytical Method Code	The identification code of the analytical method used.
16. Extraction Batch Identification Code.	Laboratory assigned extraction batch ID. Must be unique for each extraction batch within the laboratory for each method. For CCC samples report the Analysis Batch Identification Code as the value for this field. For methods without an extraction batch, leave this field null.

TABLE 1 TO PARAGRAPH (e)—UNREGULATED CONTAMINANT MONITORING REPORTING REQUIREMENTS—Continued

Data element	Definition
17. Extraction Date	Date for the start of the extraction batch (YYYYMMDD). For methods without an extraction batch, leave this field null.
18. Analysis Batch Identification Code.	Laboratory assigned analysis batch ID. Must be unique for each analysis batch within the laboratory for each method.
19. Analysis Date	Date for the start of the analysis batch (YYYYMMDD).
20. Sample Analysis Type	The type of sample collected and/or prepared, as well as the fortification level. Permitted values include: CCCL = MRL level continuing calibration check; a calibration standard containing the contaminant, the internal standard, and surrogate analyzed to verify the existing calibration for those contaminants. CCCM = Medium level continuing calibration check; a calibration standard containing the contaminant, the internal standard, and surrogate analyzed to verify the existing calibration for those contaminants. CCCH = High level continuing calibration check; a calibration standard containing the contaminant, the internal standard, and surrogate analyzed to verify the existing calibration for those contaminants. FS = Field sample; sample collected and submitted for analysis under this final rule. LFB = Laboratory fortified blank; an aliquot of reagent water fortified with known quantities of the contaminants and all preservation compounds. LRB = Laboratory reagent blank; an aliquot of reagent water treated exactly as a field sample, including the addition of preservatives, internal standards, and surrogates to determine if interferences are present in the laboratory, reagents, or other equipment. LFSM = Laboratory fortified sample matrix; a UCMR field sample with a known amount of the contaminant of interest and all preservation compounds added. LFSMD = Laboratory fortified sample matrix duplicate; duplicate of the laboratory fortified sample matrix. QCS = Quality control sample; a sample prepared with a source external to the one used for initial calibration and CCC. The QCS is used to check calibration standard integrity. FRB = Field reagent blank; an aliquot of reagent water treated as a sample including exposure to sampling conditions to determine if interferences or contamination are present from sample collection through analysis.
21. Analytical Result—Sign	A value indicating whether the sample analysis result was: (<) ''less than'' means the contaminant was not detected, or was detected at a level below the Minimum Reporting Level. (=) ''equal to'' means the contaminant was detected at the level reported in ''Analytical Result— Measured Value.''
22. Analytical Result—Measured Value.	The actual numeric value of the analytical results for: Field samples; laboratory fortified matrix samples; laboratory fortified sample matrix duplicates; and concentration fortified.
23. Additional Value	Represents the true value or the fortified concentration for spiked samples for QC Sample Analysis Types (CCCL, CCCM, CCCH, QCS, LFB, LFSM, and LFSMD).
24. Laboratory Identification Code	The code, assigned by EPA, used to identify each laboratory. The code begins with the standard two-character State postal abbreviation; the remaining five numbers are unique to each laboratory in the State.
25. Sample Event Code	A code assigned by the PWS for each sample event. This will associate samples with the PWS monitoring plan to allow EPA to track compliance and completeness. Systems must assign the following codes: SE1, SE2, SE3, and SE4—Represent samples collected to meet UCMR Assessment Monitoring requirements; where ''SE1'' and ''SE2'' represent the first and second sampling period for all water types; and ''SE3'' and ''SE4'' represent the third and fourth sampling period for SW, GU, and MX sources only.
26. Historical Information for Contaminant Detections and Treatment.	A yes or no answer provided by the PWS for each entry point to the distribution system. Question: Have you tested for the contaminant in your drinking water in the past? YES = If yes, did you modify your treatment and if so, what types of treatment did you implement? Select all that apply. PAC = Application of powder activated carbon. GAC = Granular activated carbon adsorption (not part of filters in CON, SFN, INF, DFL, or SSF). IEX = Ionic exchange. NRO = Nanofiltration and reverse osmosis. OZN = Ozone. BAC = Biologically active carbon. MFL = Membrane filtration. UVL = Ultraviolet light. OTH = Other. NMT = Not modified after testing. NO = Have never tested for the contaminant. DK = Do not know.
27. Potential PFAS Sources	A yes or no answer provided by the PWS for each entry point to the distribution system. Question: Are you aware of any potential current and/or historical sources of PFAS that may have impacted the drinking water sources at your water system? YES = If yes, select all that apply: MB = Military base. FT = Firefighting training school. AO = Airport operations. CW = Car wash or industrial launderers. PS = Public safety activities (*e.g.,* fire and rescue services). WM = Waste management. HW = Hazardous waste collection, treatment, and disposal. UW = Underground injection well. SC = Solid waste collection, combustors, incinerators. MF = Manufacturing.

TABLE 1 TO PARAGRAPH (e)—UNREGULATED CONTAMINANT MONITORING REPORTING REQUIREMENTS—Continued

Data element	Definition
	FP = Food packaging. TA = Textile and apparel (*e.g.,* stain- and water-resistant, fiber/thread, carpet, house furnishings, leather). PP = Paper. CC = Chemical. PR = Plastics and rubber products. MM = Machinery. CE = Computer and electronic products. FM = Fabricated metal products (e.g., nonstick cookware). PC = Petroleum and coal products. FF = Furniture. OG = Oil and gas production. UT = Utilities (e.g., sewage treatment facilities). CT = Construction (e.g., wood floor finishing, electrostatic painting). OT = Other. NO = Not aware of any potential current and/or historical sources. DK = Do not know.

Subpart E—Special Regulations, Including Monitoring Regulations and Prohibition on Lead Use

■ 3. Amend § 141.40 as follows:
■ a. In paragraph (a) introductory text, remove the text ''December 31, 2015'' and add in its place the text ''February 1, 2021 or subsequent corrections from the State'';
■ b. Revise paragraphs (a)(2)(ii) introductory text, (a)(2)(ii)(A), and (a)(3);
■ c. In paragraph (a)(4)(i) introductory text, remove the text ''December 31, 2017'' and add in its place the text ''December 31, 2022'';
■ d. Revise paragraphs (a)(4)(i)(A) through (C), (a)(4)(ii) introductory text, and the first sentence in paragraph (a)(4)(ii)(A);
■ e. Remove paragraph (a)(4)(iii);
■ f. In paragraph (a)(5)(ii), revise the fifth and sixth sentences;
■ g. Revise paragraph (a)(5)(iii) introductory text;
■ h. Remove and reserve paragraph (a)(5)(iv); and
■ i. Revise paragraphs (a)(5)(v) and (vi) and paragraph (c).

The revisions read as follows:

§ 141.40 Monitoring requirements for unregulated contaminants.

(a) * * *

(2) * * *

(ii) *Small systems.* EPA will provide sample containers, provide pre-paid air bills for shipping the sampling materials, conduct the laboratory analysis, and report and review monitoring results for all small systems selected to conduct monitoring under paragraphs (a)(2)(ii)(A) through (C) of this section. If you own or operate a PWS (other than a transient non-community water system) that serves a retail population of 10,000 or fewer people and you are notified of monitoring requirements by the State or EPA, you must monitor as follows:

(A) *Assessment Monitoring.* You must monitor for the contaminants on List 1 per table 1 to paragraph (a)(3) if you are notified by your State or EPA that you are part of the State Monitoring Plan for Assessment Monitoring.

* * * * *

(3) *Analytes to be monitored.* Lists 1, 2, and 3 contaminants are provided in table 1 to paragraph (a)(3):

TABLE 1 TO PARAGRAPH (a)(3)—UCMR CONTAMINANT LIST

1—Contaminant	2—CASRN	3—Analytical methods [a]	4—Minimum reporting level [b]	5—Sampling location [c]	6—Period during which sample collection to be completed
List 1: Assessment Monitoring					
Per- and Polyfluoroalkyl Substances (PFAS)					
11-chloroeicosafluoro-3-oxaundecane-1-sulfonic acid (11Cl-PF3OUdS).	763051–92–9	EPA 533	0.005 µg/L	EPTDS	1/1/2023–12/31/2025
1H, 1H, 2H, 2H-perfluorodecane sulfonic acid (8:2 FTS).	39108–34–4	EPA 533	0.005 µg/L	EPTDS	1/1/2023–12/31/2025
1H, 1H, 2H, 2H-perfluorohexane sulfonic acid (4:2 FTS).	757124–72–4	EPA 533	0.003 µg/L	EPTDS	1/1/2023–12/31/2025
1H, 1H, 2H, 2H-perfluorooctane sulfonic acid (6:2 FTS).	27619–97–2	EPA 533	0.005 µg/L	EPTDS	1/1/2023–12/31/2025
4,8-dioxa-3H-perfluorononanoic acid (ADONA).	919005–14–4	EPA 533	0.003 µg/L	EPTDS	1/1/2023–12/31/2025
9-chlorohexadecafluoro-3-oxanone-1-sulfonic acid (9Cl-PF3ONS).	756426–58–1	EPA 533	0.002 µg/L	EPTDS	1/1/2023–12/31/2025
hexafluoropropylene oxide dimer acid (HFPO-DA) (GenX).	13252–13–6	EPA 533	0.005 µg/L	EPTDS	1/1/2023–12/31/2025
nonafluoro-3,6-dioxaheptanoic acid (NFDHA)	151772–58–6	EPA 533	0.02 µg/L	EPTDS	1/1/2023–12/31/2025
perfluoro (2-ethoxyethane) sulfonic acid (PFEESA).	113507–82–7	EPA 533	0.003 µg/L	EPTDS	1/1/2023–12/31/2025
perfluoro-3-methoxypropanoic acid (PFMPA)	377–73–1	EPA 533	0.004 µg/L	EPTDS	1/1/2023–12/31/2025
perfluoro-4-methoxybutanoic acid (PFMBA)	863090–89–5	EPA 533	0.003 µg/L	EPTDS	1/1/2023–12/31/2025
perfluorobutanesulfonic acid (PFBS)	375–73–5	EPA 533	0.003 µg/L	EPTDS	1/1/2023–12/31/2025
perfluorobutanoic acid (PFBA)	375–22–4	EPA 533	0.005 µg/L	EPTDS	1/1/2023–12/31/2025

TABLE 1 TO PARAGRAPH (a)(3)—UCMR CONTAMINANT LIST—Continued

1—Contaminant	2—CASRN	3—Analytical methods [a]	4—Minimum reporting level [b]	5—Sampling location [c]	6—Period during which sample collection to be completed
perfluorodecanoic acid (PFDA)	335–76–2	EPA 533	0.003 μg/L	EPTDS	1/1/2023–12/31/2025
perfluorododecanoic acid (PFDoA)	307–55–1	EPA 533	0.003 μg/L	EPTDS	1/1/2023–12/31/2025
perfluoroheptanesulfonic acid (PFHpS)	375–92–8	EPA 533	0.003 μg/L	EPTDS	1/1/2023–12/31/2025
perfluoroheptanoic acid (PFHpA)	375–85–9	EPA 533	0.003 μg/L	EPTDS	1/1/2023–12/31/2025
perfluorohexanesulfonic acid (PFHxS)	355–46–4	EPA 533	0.003 μg/L	EPTDS	1/1/2023–12/31/2025
perfluorohexanoic acid (PFHxA)	307–24–4	EPA 533	0.003 μg/L	EPTDS	1/1/2023–12/31/2025
perfluorononanoic acid (PFNA)	375–95–1	EPA 533	0.004 μg/L	EPTDS	1/1/2023–12/31/2025
perfluorooctanesulfonic acid (PFOS)	1763–23–1	EPA 533	0.004 μg/L	EPTDS	1/1/2023–12/31/2025
perfluorooctanoic acid (PFOA)	335–67–1	EPA 533	0.004 μg/L	EPTDS	1/1/2023–12/31/2025
perfluoropentanesulfonic acid (PFPeS)	2706–91–4	EPA 533	0.004 μg/L	EPTDS	1/1/2023–12/31/2025
perfluoropentanoic acid (PFPeA)	2706–90–3	EPA 533	0.003 μg/L	EPTDS	1/1/2023–12/31/2025
perfluoroundecanoic acid (PFUnA)	2058–94–8	EPA 533	0.002 μg/L	EPTDS	1/1/2023–12/31/2025
n-ethyl perfluorooctanesulfonamidoacetic acid (NEtFOSAA).	2991–50–6	EPA 537.1	0.005 μg/L	EPTDS	1/1/2023–12/31/2025
n-methyl perfluorooctanesulfonamidoacetic acid (NMeFOSAA).	2355–31–9	EPA 537.1	0.006 μg/L	EPTDS	1/1/2023–12/31/2025
perfluorotetradecanoic acid (PFTA)	376–06–7	EPA 537.1	0.008 μg/L	EPTDS	1/1/2023–12/31/2025
perfluorotridecanoic acid (PFTrDA)	72629–94–8	EPA 537.1	0.007 μg/L	EPTDS	1/1/2023–12/31/2025
Metal/Pharmaceutical					
Lithium	7439–93–2	EPA 200.7, SM 3120 B, ASTM D1976–20.	9 μg/L	EPTDS	1/1/2023–12/31/2025
List 2: Screening Survey					
Reserved	Reserved	Reserved	Reserved	Reserved	Reserved
List 3: Pre-Screen Testing					
Reserved	Reserved	Reserved	Reserved	Reserved	Reserved

Column headings are:
1—Contaminant: The name of the contaminant to be analyzed.
2—CASRN (Chemical Abstracts Service Registry Number) or Identification Number: A unique number identifying the chemical contaminants.
3—Analytical Methods: Method numbers identifying the methods that must be used to test the contaminants.
4—Minimum Reporting Level (MRL): The value and unit of measure at or above which the concentration of the contaminant must be measured using the approved analytical methods. If EPA determines, after the first six months of monitoring that the specified MRLs result in excessive resampling, EPA will establish alternate MRLs and will notify affected PWSs and laboratories of the new MRLs. N/A is defined as non-applicable.
5—Sampling Location: The locations within a PWS at which samples must be collected.
6—Period During Which Sample Collection to be Completed: The time period during which the sampling and testing will occur for the indicated contaminant.
[a] The analytical procedures shall be performed in accordance with the documents associated with each method, see paragraph (c) of this section.
[b] The MRL is the minimum concentration of each analyte that must be reported to EPA.
[c] Sampling must occur at your PWS's entry points to the distribution system (EPTDSs), after treatment is applied, that represent each non-emergency water source in routine use over the 12-month period of monitoring. Systems that purchase water with multiple connections from the same wholesaler may select one representative connection from that wholesaler. The representative EPTDS must be a location within the purchaser's water system. This EPTDS sampling location must be representative of the highest annual volume connections. If the connection selected as the representative EPTDS is not available for sampling, an alternate highest volume representative connection must be sampled. See 40 CFR 141.35(c)(3) for an explanation of the requirements related to the use of representative GW EPTDSs.

(4) * * *
(i) * * *

(A) *Sample collection period.* You must collect the samples in one continuous 12-month period for List 1 Assessment Monitoring, and, if applicable, for List 2 Screening Survey, or List 3 Pre-Screen Testing, during the timeframe indicated in column 6 of table 1 to paragraph (a)(3) of this section. EPA or your State will specify the month(s) and year(s) in which your monitoring must occur. As specified in 40 CFR 141.35(c)(5), you must contact EPA if you believe you cannot collect samples according to your schedule.

(B) *Frequency.* You must collect the samples within the timeframe and according to the frequency specified by contaminant type and water source type for each sampling location, as specified in table 2 to this paragraph (a)(4)(i)(B). For the second or subsequent round of sampling, if a sample location is non-operational for more than one month before and one month after the scheduled sampling month (*i.e.,* it is not possible for you to sample within the window specified in table 2), you must notify EPA as specified in 40 CFR 141.35(c)(5) to reschedule your sampling.

TABLE 2 TO PARAGRAPH (a)(4)(i)(B)—MONITORING FREQUENCY BY CONTAMINANT AND WATER SOURCE TYPES

Contaminant type	Water source type	Timeframe	Frequency [1]
List 1 Contaminants	Surface water, Mixed, or GWUDI.	12 months	You must monitor for four consecutive quarters. Sample events must occur three months apart. (Example: If first monitoring is in January, the second monitoring must occur any time in April, the third any time in July, and the fourth any time in October).
	Ground water	12 months	You must monitor twice in a consecutive 12-month period. Sample events must occur 5–7 months apart. (Example: If the first monitoring event is in April, the second monitoring event must occur any time in September, October, or November.)

[1] Systems must assign a sample event code for each contaminant listed in Table 1. Sample event codes must be assigned by the PWS for each sample event. For more information on sample event codes see 40 CFR 141.35(e) Table 1.

(C) *Location.* You must collect samples for each List 1 Assessment Monitoring contaminant, and, if applicable, for each List 2 Screening Survey, or List 3 Pre-Screen Testing contaminant, as specified in table 1 to paragraph (a)(3) of this section. Samples must be collected at each sample point that is specified in column 5 and footnote c of table 1 to paragraph (a)(3) of this section. If you are a GW system with multiple EPTDSs, and you request and receive approval from EPA or the State for sampling at representative EPTDS(s), as specified in 40 CFR 141.35(c)(3), you must collect your samples from the approved representative sampling location(s).

* * * * *

(ii) *Small systems.* If you serve a population of 10,000 or fewer people and are notified that you are part of the State Monitoring Plan, you must comply with the requirements specified in paragraphs (a)(4)(ii)(A) through (H) of this section. If EPA or the State informs you that they will be collecting your UCMR samples, you must assist them in identifying the appropriate sampling locations and in collecting the samples.

(A) *Sample collection and frequency.* You must collect samples at the times specified for you by the State or EPA. Your schedule must follow both the timing of monitoring specified in table 1 to paragraph (a)(3) of this section, List 1, and, if applicable, List 2, or List 3, and the frequency of monitoring in table 2 to paragraph (a)(4)(i)(B) of this section.

* * * * *

(5) * * *

(ii) * * * To participate in the UCMR Laboratory Approval Program, the laboratory must register and complete the necessary application materials by August 1, 2022. Correspondence must be addressed to: UCMR Laboratory Approval Coordinator, USEPA, Technical Support Center, 26 West Martin Luther King Drive, (MS 140), Cincinnati, Ohio 45268; or emailed to EPA at: *UCMR_Lab_Approval@epa.gov.*

(iii) *Minimum Reporting Level.* The MRL is defined by EPA as the quantitation limit achievable, with 95 percent confidence, by 75 percent of laboratories nationwide, assuming the use of good instrumentation and experienced analysts.

* * * * *

(v) *Method defined quality control.* You must ensure that your laboratory analyzes Laboratory Fortified Blanks and conducts Laboratory Performance Checks, as appropriate to the method's requirements, for those methods listed in column 3 in table 1 to paragraph (a)(3) of this section. Each method specifies acceptance criteria for these QC checks.

(vi) *Reporting.* You must require your laboratory, on your behalf, to post and approve these data in EPA's electronic data reporting system, accessible at *https://www.epa.gov/dwucmr,* for your review within 90 days from the sample collection date. You then have 30 days from when the laboratory posts and approves your data to review, approve, and submit the data to the State and EPA, via the agency's electronic data reporting system. If you do not electronically approve and submit the laboratory data to EPA within 30 days of the laboratory posting approved data, the data will be considered approved by you and available for State and EPA review.

* * * * *

(c) *Incorporation by reference.* The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at U.S. Environmental Protection Agency, Water Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20004, (202) 566–1744, email *Docket-customerservice@epa.gov,* or go to *https://www.epa.gov/dockets/epa-docket-center-reading-room,* and is available from the sources indicated elsewhere in this paragraph. The material is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to *www.archives.gov/federal-register/cfr/ibr-locations.html.*

(1) U.S. Environmental Protection Agency, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20004; telephone: (202) 566–1744.

(i) Method 200.7, ''Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry,'' Revision 4.4, EMMC Version, 1994. Available at *https://www.epa.gov/esam/method-2007-determination-metals-and-trace-elements-water-and-wastes-inductively-coupled-plasma.*

(ii) Method 537.1, ''Determination of Selected Per- and Polyfluorinated Alkyl Substances in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry,'' Version 2.0, 2020. Available at *https://www.epa.gov/water-research/epa-drinking-water-research-methods.*

(iii) Method 533, ''Determination of Per- and Polyfluoroalkyl Substances in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry,'' November 2019, EPA 815–B–19–020. Available at *https://www.epa.gov/dwanalyticalmethods.*

(2) American Public Health Association, 800 I Street NW, Washington, DC 20001–3710; telephone: (202) 777–2742; email: *comments@apha.org; www.apha.org.*

(i) ''Standard Methods for the Examination of Water & Wastewater,'' 23rd edition (2017).

(A) SM 3120 B, ''Metals by Plasma Emission Spectroscopy (2017): Inductively Coupled Plasma (ICP) Method.''

(B) [Reserved]

(ii) ''Standard Methods Online,'' approved 1999; *https://www.standardmethods.org.*

(A) SM 3120 B, ''Metals by Plasma Emission Spectroscopy: Inductively Coupled Plasma (ICP) Method,'' revised December 14, 2020.

(B) [Reserved]

(3) ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959; telephone: (610) 832–9500; email: *service@astm.org; www.astm.org.*

(i) ASTM D1976–20, ''Standard Test Method for Elements in Water by Inductively-Coupled Plasma Atomic Emission Spectroscopy,'' approved May 1, 2020.

(ii) [Reserved]

[FR Doc. 2021–27858 Filed 12–23–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 405, 410, 411, 414, 415, 423, 424, and 425

[CMS–1751–CN]

RIN 0938–AU42

Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule; correction.

SUMMARY: This document corrects technical errors that appeared in the final rule published in the **Federal Register** on November 19, 2021 entitled ''Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; and Provider and Supplier Prepayment and Post-Payment Medical Review Requirements'' (referred to hereafter as the ''CY 2022 PFS final rule''). The effective date of the CY 2022 PFS final rule is January 1, 2022.

DATES: This correction is effective January 1, 2022.

FOR FURTHER INFORMATION CONTACT: Terri Plumb, (410) 786–4481, Gaysha Brooks, (410) 786–9649, or Annette Brewer (410) 786–6580.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2021–23972 of November 19, 2021, the CY 2022 PFS final rule (86 FR 64996), there were technical errors that are identified and corrected in this correcting document. These corrections are effective as if they had been included in the CY 2022 PFS final rule. Accordingly, the corrections are effective January 1, 2022.

II. Summary of Errors

A. Summary of Errors in the Preamble

On page 65320, in Table 39: MDPP Payment Structure, lines 7 and 9, we made typographical errors in the final payment rate for Core Maintenance (CM) Session (Months 7–12) for entries Attend 2 Core Maintenance Sessions (No 5% WL) in CM Interval 1 (Months 7–9)) and (Attend 2 Core Maintenance Sessions (No 5% WL) in CM Interval 2 (Months 10–12)).

On page 65324, second column, first partial paragraph, line 26, we made a typographical error in the core maintenance sessions amount.

B. Summary of Errors in the Regulations Text

On page 65668, third column, line 4 contains a typographical error.

On page 65670, second column, line 41 contains a typographical error in the paragraph designation.

On page 65670, second column, lines 44 through 45 contain a typographical error in the paragraph designation.

On page 65673, third column, lines 4 through 5 contain typographical errors.

On page 65673, third column, lines 57 through 58 contain typographical errors.

On page 65673, third column, line 66 contains typographical errors.

C. Summary of Errors in the Addenda

On page 65702, B.1 Allergy/Immunology, eighth column, second full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 6, contains a typographical error.

On page 65725, B.9 Dermatology, eighth column, second full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 7, contains a typographical error.

On page 65730, B.11 Emergency Medicine, eighth column, seventh full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 6, contains a typographical error.

On page 65743, B.13 Family Medicine, eighth column, first full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 8, contains a typographical error.

On page 65751, B.14 Gastroenterology, eighth column, third full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 7, contains a typographical error.

On page 65753, B.15 General Surgery, eighth column, sixth full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 6, contains a typographical error.

On page 65768, B.19 Internal Medicine, eighth column, fifth full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, lines 7 and 8, contain a typographical error.

On page 65779, B.21 Mental/Behavioral, eighth column, third full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 7, contains a typographical error.

On page 65783, B.22 Nephrology, eighth column, third full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 7, contains a typographical error.

On page 65787, B.23 Neurology, eighth column, seventh full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 7, contains a typographical error.

On page 65800, B.26 Obstetrics/Gynecology, eighth column, third full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 10, contains a typographical error.

On page 65805, B.27 Oncology/Hematology, eighth column, fifth full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 8, contains a typographical error.

On page 65817, B.29 Orthopedic Surgery, eighth column, second full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 8, contains a typographical error.

On page 65824, B.30 Otolaryngology, eighth column, second full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, lines 7 and 8, contain a typographical error.

On page 65833, B.33 Physical Medicine, eighth column, second full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, lines 7 and 8, contain a typographical error.

On page 65841, B.35 Plastic Surgery eighth column, third full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, lines 7 and 8, contain a typographical error.

On page 65849, B.37 Preventive Medicine, eighth column, second full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, lines 7 and 8, contain a typographical error.

On page 65856, B.39 Rheumatology, eighth column, fourth full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 7, contains a typographical error.

On page 65859, B.40 Skilled Nursing Facility, eighth column, fifth full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 6, contains a typographical error.

On page 65865, B.42 Thoracic Surgery, seventh column, fourth full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, lines 8 and 9, contain a typographical error.

On page 65867, B.43 Urgent Care, eighth column, second full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, lines 7 and 8, contain a typographical error.

On page 65870, B.44 Urology, eighth column, fifth full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 7, contains a typographical error.

On page 65875, B.45 Vascular Surgery, eighth column, fifth full row, Preventive Care and Screening: Screening for High Blood Pressure and

Follow-up Documented, line 7, contains a typographical error.

On page 65967, D.87: Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, the Current Measure Description for Quality # 317 contains a typographical error.

On page 65979, Table B: Changes to Previously Adopted Improvement Activities for the CY 2022 Performance Period/2024 MIPS Payment Year and Future Years, second column, fifth full row, an inadvertent error was made noting the current weighting of this Current Improvement Activity.

On page 65980, Table B: Changes to Previously Adopted Improvement Activities for the CY 2022 Performance Period/2024 MIPS Payment Year and Future Years, second column, fifth full row, an inadvertent error was made noting the weighting of this Finalized Improvement Activity.

On page 65998, footnote 287, an inadvertent error was made noting the section of the rule regarding the MVP implementation timeline.

III. Waiver of Proposed Rulemaking

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (the APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Social Security Act (the Act) requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. In addition, section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act mandate a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the APA notice and comment, and delay in effective date requirements; in cases in which these exceptions apply, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act provide exceptions from the notice and 60-day comment period and delay in effective date requirements of the Act as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal notice and comment rulemaking procedures for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and includes a statement of the finding and the reasons for it in the rule. In addition, section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) allow the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and the agency includes in the rule a statement of the finding and the reasons for it.

In our view, this correcting document does not constitute a rulemaking that would be subject to these requirements. This document merely corrects technical errors in the CY 2022 PFS final rule. The corrections contained in this document are consistent with, and do not make substantive changes to, the policies and payment methodologies that were proposed, subject to notice and comment procedures, and adopted in the CY 2022 PFS final rule. As a result, the corrections made through this correcting document are intended to resolve inadvertent errors so that the rule accurately reflects the policies adopted in the final rule. Even if this were a rulemaking to which the notice and comment and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the CY 2022 PFS final rule or delaying the effective date of the corrections would be contrary to the public interest because it is in the public interest to ensure that the rule accurately reflects our policies as of the date they take effect. Further, such procedures would be unnecessary because we are not making any substantive revisions to the final rule, but rather, we are simply correcting the **Federal Register** document to reflect the policies that we previously proposed, received public comment on, and subsequently finalized in the final rule. For these reasons, we believe there is good cause to waive the requirements for notice and comment and delay in effective date.

IV. Correction of Errors

In FR Doc. 2021–23972 of November 19, 2021 (86 FR 64996) make the following corrections:

A. Correction of Errors in the Preamble

1. On page 65320, in Table 39: MDPP Payment Structure, lines 7 and 9, the listed entries are corrected to read as follows:

Core Maintenance (CM) Sessions (Months 7–12)			
Attend 2 Core Maintenance Sessions (No 5% WL) in CM Interval 1 (Months 7–9)	$15	$52	$70
Attend 2 Core Maintenance Sessions (No 5% WL) in CM Interval 2 (Months 10–12)	$15	$52	$70

2. On page 65324, second column, first partial paragraph, line 26, the phrase that reads ''sessions to from $52.00 to $75.00.'' is corrected to read ''sessions from $52.00 to $70.00.''

B. Correction of Errors in the Regulations Text

§ 414.84 [Corrected]

■ 1. On page 65668, third column, in § 414.84, in paragraph (b)(4)(ii)(A), the text ''December 31, 2022 the amount is $75'' is corrected to read ''December 31, 2022 the amount is $70.''.

§ 414.1305 [Corrected]

■ 2. On page 65670, second column, in § 414.1305, in the definition of ''MIPS eligible clinician,'' the second paragraph (3)(ii) and paragraph (3)(vii) are redesignated as paragraphs (3)(iii) and (iv), respectively.

§ 414.1380 [Corrected]

■ 3. On page 65673, third column, in § 414.1380:

■ i. In paragraph (b)(1)(i) introductory text, the text ''the CY 2017 through 2021 performance periods/2019 through 2023 MIPS'' is corrected to read ''the CY 2017 through 2022 performance periods/2019 through 2024 MIPS''.

■ ii. In paragraph (b)(1)(i)(A)(*1*):

■ A. The text ''the CY 2017 through 2021 MIPS performance periods/2019 through 2023'' is corrected to read ''the CY 2017 through 2022 performance periods/2019 through 2024''.

■ B. The text ''CY 2022 performance period/2024'' is corrected to read ''the CY 2023 performance period/2025''.

C. Correction of Errors in the Addenda

1. On page 65702, B.1 Allergy/Immunology, eighth column, second full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 6, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

2. On page 65725, B.9 Dermatology, eighth column, second full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 7, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

3. On page 65730, B.11 Emergency Medicine, eighth column, seventh full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 6, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

4. On page 65743, B.13 Family Medicine, eighth column, first full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 8, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

5. On page 65751, B.14 Gastroenterology, eighth column, third full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 7, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

6. On page 65753, B.15 General Surgery, eighth column, sixth full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 6, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

7. On page 65768, B.19 Internal Medicine, eighth column, fifth full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, lines 7 and 8, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

8. On page 65779, B.21 Mental/Behavioral, eighth column, third full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 7, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

9. On page 65783, B.22 Nephrology, eighth column, third full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 7, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

10. On page 65787, B.23 Neurology, eighth column, seventh full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 7, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

11. On page 65800, B.26 Obstetrics/Gynecology, eighth column, third full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 10, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

12. On page 65805, B.27 Oncology/Hematology, eighth column, fifth full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 8, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

13. On page 65817, B.29 Orthopedic Surgery, eighth column, second full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 8, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

14. On page 65824, B.30 Otolaryngology, eighth column, second full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, lines 7 and 8, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

15. On page 65833, B.33 Physical Medicine, eighth column, second full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, lines 7 and 8, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

16. On page 65841, B.35 Plastic Surgery eighth column, third full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, lines 7 and 8, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

17. On page 65849, B.37 Preventive Medicine, eighth column, second full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, lines 7 and 8, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

18. On page 65856, B.39 Rheumatology, eighth column, fourth full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 7, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

19. On page 65859, B.40 Skilled Nursing Facility, eighth column, fifth full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 6, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

20. On page 65865, B.42 Thoracic Surgery, seventh column, fourth full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, lines 8 and 9, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

21. On page 65867, B.43 Urgent Care, eighth column, second full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, lines 7 and 8, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

22. On page 65870, B.44 Urology, eighth column, fifth full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 7, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

23. On page 65875, B.45 Vascular Surgery, eighth column, fifth full row, Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, line 7, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

24. On page 65967, D.87: Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented, second column, Description, sixth full row, Current Measure Description, line 2, the phrase ''pre-hypertensive'' is corrected to read ''elevated''.

25. On page 65979, Table B: Changes to Previously Adopted Improvement Activities for the CY 2022 Performance Period/2024 MIPS Payment Year and Future Years, second column, IA_AHE_1, fifth full row, of this Current Improvement Activity, Current Weighting, the phrase ''Medium'' should be corrected to read ''High''.

26. On page 65980, Table B: Changes to Previously Adopted Improvement Activities for the CY 2022 Performance Period/2024 MIPS Payment Year and Future Years, second column, IA_AHE_1, fifth full row, of this Finalized Improvement Activity, Weighting, the phrase ''Medium'' should be corrected to read ''High''.

27. On page 65998, footnote 287, that reads ''See section IV.A.3.b.(2)(d) of this final rule for additional details regarding the MVP implementation timeline'' is corrected to read: ''See section IV.A.3.b.(2)(c) of this final rule for additional details regarding the MVP implementation timeline.''

Karuna Seshasai,

Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2021–27853 Filed 12–23–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Parts 114, 116, 118, 122, 175, 177, 181, and 185

[Docket No. USCG–2021–0306]

RIN 1625–AC69

Fire Safety of Small Passenger Vessels

AGENCY: Coast Guard, DHS.

ACTION: Interim rule.

SUMMARY: The Coast Guard is issuing an interim rule as the first step to

implementing the statutorily mandated requirements for fire safety on certain covered small passenger vessels. This statutory mandate is in response to the fire and loss of life on the dive boat *CONCEPTION* off the coast of California on September 2, 2019. This interim rule adds additional fire safety requirements for small passenger vessels, including fire detection and suppression systems, avenues of escape, egress drills, crew firefighting training, watchmen monitoring devices, and the handling of flammable items such as rechargeable batteries.

DATES: This interim rule is effective March 28, 2022, except for amendatory instruction numbers 13, 14, 29, and 31 adding of § 122.507(b), amending 122.515, adding 185.507(b), and adding 185.515(a), respectively, which are delayed indefinitely. The Coast Guard will publish a document in the **Federal Register** announcing the effective date of those additions. Comments and related material must be received by the Coast Guard on or before June 27, 2022. Comments on the collection of information must be received by the Coast Guard on or before January 26, 2022. The incorporation by reference of the material in § 181.450 was approved by the Director of the Federal Register as of March 11, 1996.

ADDRESSES: You may submit comments identified by docket number USCG–2021–0306 using the Federal Decision Making Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments. To view documents mentioned in this interim rule as being available in the docket, search the docket number USCG–2021–0306 using the Federal eRulemaking Portal at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For information about this document, call or email Lieutenant Carmine Faul, Coast Guard; telephone 202–475–1357, email *carmine.a.faul@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Table of Contents for Preamble

I. Abbreviations

2020 CGAA Elijah E. Cummings Coast Guard Authorization Act of 2020
DHS Department of Homeland Security
CFR Code of Federal Regulations
FR Federal Register
IBR Incorporated by Reference
NPRM Notice of proposed rulemaking
NRTL Nationally recognized testing laboratory
NTSB National Transportation Safety Board
OCMI Officer in Charge, Marine Inspection
OMB Office of Management and Budget
§ Section
SPV Small passenger vessel
UL Underwriter Laboratories
U.S.C. United States Code

II. Basis and Purpose

Section 8441 of the Elijah E. Cummings Coast Guard Authorization Act of 2020 (2020 CGAA) amended Title 46 of the United States Code (U.S.C.), section 3306, which now directs the Secretary of the Department of Homeland Security (DHS) to prescribe fire safety regulations for certain ''covered small passenger vessels,'' defined as small passenger vessels (SPVs) with overnight accommodations for passengers or operating on Oceans or Coastwise routes, excluding fishing vessels and ferries. (See Pub. L. 116–283, January 1, 2021.) The 2020 CGAA added a new paragraph (n) to section 3306 which requires the Secretary to issue interim requirements to cover the following eight provisions:

1. Marine firefighting training programs to improve crewmember training and proficiency, including egress training for each member of the crew;

2. Interconnected fire detection equipment and additional fire extinguishers and firefighting equipment in all areas on board where passengers and crew have access;

3. Installation and use of monitoring devices to ensure wakefulness of the required night watch (for covered SPVs with overnight passenger accommodations);

4. Increased fire detection and suppression systems in unmanned areas with machinery or areas with other potential heat sources;

5. No less than two independent avenues of escape for all general areas accessible to passengers, that are constructed and arranged to allow for unobstructed egress, located so that if one avenue of escape is not available, another avenue of escape is available, and not directly above, or dependent on, a berth (for covered SPVs with overnight passenger accommodations);

6. Handling, storage, and operation of flammable items, such as rechargeable batteries, including lithium-ion batteries;

7. Requirements for passenger emergency egress drills (for covered SPVs with overnight passenger accommodations); and

8. Providing all passengers a copy of the emergency egress plan for the vessel (for covered SPVs with overnight passenger accommodations).

Section 46 U.S.C. 3306(n) requires that the Secretary perform a comprehensive review of all existing requirements for fire detection, protection, and suppression systems, and avenues of egress on covered SPVs to support the rulemaking. Prior to completing the comprehensive review and issuing final regulations, Section 46 U.S.C. 3306(n) requires that the Secretary implement interim requirements to enforce the fire safety provisions listed in Section 46 U.S.C. 3306(n)(3), which is the subject of this interim rule. The Secretary delegated the statutory authority to promulgate regulations related to passenger safety on vessels to the Coast Guard through DHS Delegation No. 00170.1(92)(b), Revision No. 01.2.

Section 3306(n)(4)(B) exempts the Coast Guard's implementation of the interim requirements from compliance with Chapters 5 and 6 of 5 U.S.C., and from Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review). This means that the interim requirements are exempt from several common rulemaking procedural steps, including:

- The public notice and comment requirements of the Administrative Procedure Act;
- The economic analysis requirements of the Regulatory Flexibility Act;
- The Unified Agenda, significance determination, and the Office of Information and Regulatory Affairs review requirements of Executive Order 12866; and
- Executive Order 13563 requirements that the rule impose the least burden and maximize net benefits.

The exemptions provided in the 2020 CGAA do not cover all the laws and Executive orders that potentially apply to rulemaking. The **Federal Register** Act, Paperwork Reduction Act, National Environmental Policy Act, and various Executive orders, such as those on Federalism, tribal consultation, and taking of property still apply and are

considered in this preamble. We are issuing an interim rule with request for public comment to implement the interim requirements. In the future, we plan to issue final regulations after consideration of public comment and relevant matter presented from our comprehensive review. The comprehensive review will incorporate both technical and economic benefit-cost considerations not required to be addressed in this interim rule.

III. Background and Regulatory History

The mandates in 46 U.S.C. 3306(n) are an outcome of the fire onboard the 75-foot dive boat *CONCEPTION* on September 2, 2019, off the coast of Santa Cruz Island, California, resulting in the deaths of 34 persons. At approximately 3 a.m., fire broke out on the main deck directly above the lower deck berthing area where the 33 passengers and 1 crewmember were sleeping and ultimately perished.

The National Transportation Safety Board (NTSB) conducted an investigation of the incident and stated in its Marine Accident Report that, ''the probable cause of the accident on board the SPV *CONCEPTION* was the failure of Truth Aquatics, Inc. to provide effective oversight of its vessel and crewmember operations, including requirements to ensure that a roving patrol was maintained, which allowed a fire of unknown cause to grow, undetected, in the vicinity of the aft salon on the main deck.'' [1] The NTSB determined that other contributing causes were inadequate smoke detection and inadequate egress arrangements. While the cause of the fire remains unknown, potential sources of ignition noted by the NTSB include malfunctioning lithium-ion batteries and overloading electrical circuits due to excessively connecting a series of rechargeable devices together using a single connection.

Furthermore, the NTSB issued safety recommendations to the Coast Guard in its October 20, 2020 Marine Accident Report discussing the *CONCEPTION* incident,[2] which we summarize as the following provisions:

- Revise 46 CFR Subchapter T to require all new and existing vessels with overnight accommodations to have smoke detectors in all accommodation spaces (M–20–014 & M–20–015);
- Revise Subchapters T and K to require all new and existing vessels with overnight accommodations to have interconnected smoke detectors (M–20–016);
- Develop and implement inspection procedures to verify that vessel owners, operators, and charterers are conducting roving patrols (M–20–017);
- Revise Subchapter T to require all new and existing vessels with overnight accommodations to provide secondary means of escape into a different space than the primary exit (M–20–018 & M–20–019); and
- Review suitability of Subchapter T regulations regarding means of escape for vessels constructed prior to 1996 (M–20–020).

This interim rule implements the requirements in 46 U.S.C. 3306(n)(4)(A) to add additional interim fire safety requirements for SPVs. The Coast Guard has several existing fire safety regulations for small passenger vessels in 46 CFR Subchapter K, titled ''Small Passenger Vessels Carrying More Than 150 Passengers Or With Overnight Accommodations For More Than 49 Passengers,'' and Subchapter T, titled ''Small Passenger Vessels (Under 100 Gross Tons).'' Subchapter K applies to small passenger vessels (as defined by 46 U.S.C. 2101, and implemented under Subchapter K) less than 100 GT that carry more than 150 passengers, or that have overnight accommodations for more than 49 passengers, and carry at least 1 passenger for hire. Subchapter T applies to small passenger vessels (as defined by 46 U.S.C. 2101, and implemented under Subchapter T) less than 100 GT that carry 150 or less passengers, or that have overnight accommodations for 49 or less passengers, and that carry more than 6 passengers, including at least 1 for hire.

On March 11, 1996, the Coast Guard implemented regulations generally applicable to ''new vessels'' (defined in 46 CFR 114.400 and 175.400), whereas several parts allowed ''existing vessels'' (defined in 46 CFR 114.400 and 175.400) to remain in compliance with regulations that existed on March 10, 1996. See 61 FR 864 (Jan. 10, 1996). This interim rule implements many of the statutory mandates by requiring certain small passenger vessels to come into compliance with a handful of fire safety and means of escape requirements implemented on March 11, 1996 that were previously only applicable to ''new vessels.'' This interim rule will increase the applicability of the Subchapter K and T requirements to ''existing vessels'' and also adds additional requirements, as directed by the 2020 CGAA.

Some of the terminology used in this interim rule's regulatory text and preamble varies from the terms or phrases used in 46 U.S.C. 3306(n). For the purpose of promoting consistency, this interim rule uses language and terms that are already defined or used in Subchapters K and T when applicable. For example, the Coast Guard uses the phrase ''overnight accommodations for passengers'' instead of the 46 U.S.C. 3306(n) phrase ''overnight passenger accommodations'' because ''overnight accommodations'' is already defined in Subchapters K and T in §§ 114.400 and 175.400 to capture all the relevant characteristics that would qualify a vessel as having an overnight passenger accommodation space. In this interim rule, our existing definition for ''overnight accommodation'' would apply with the qualifier ''for passengers,'' to capture only vessels with passenger overnight accommodation spaces and exclude vessels that only have crew overnight accommodation spaces. The existing definition of ''overnight accommodation'' includes an accommodation space for use by passengers that has one or more berths, including beds or bunks, for passengers to rest for extended periods. Staterooms, cabins, and berthing areas are normally overnight accommodation spaces. Overnight accommodations do not include spaces that contain only seats, including reclining seats. The term used in this interim rule, ''Overnight accommodations for passengers,'' will include all of these spaces that would normally be considered an overnight accommodation and is consistent with other usages of this phrase in Subchapters K and T. The Coast Guard adopts similar nomenclature changes to terms in 46 U.S.C. 3306(n) to be more technically precise or to align with industry and regulatory usage of the terms. We explain the differences in terminology in the following Discussion of the Rule section.

IV. Discussion of the Rule

In general, the interim rule adds the following requirements to 46 CFR subchapters T and K for vessels (that are not ferries) that operate on a Coastwise or Oceans route or have overnight accommodations for passengers. These vessels must:

[1] Fire Aboard Small Passenger Vessel Conception, Platts Harbor, Channel Islands National Park, Santa Cruz Island, 21.5 miles South-Southwest of Santa Barbara, California, September 2, 2019. Marine Accident Report. Adopted October 20, 2020. The report includes a total of 10 recommendations. *https://www.ntsb.gov/investigations/AccidentReports/Reports/MAR2003.pdf.*

[2] *Id. https://www.ntsb.gov/investigations/AccidentReports/Reports/MAR2003.pdf.* The report contains 10 recommendations total. Seven of the recommendations are directed to the Coast Guard; two recommendations are for the Passenger Vessel Association, Sportfishing Association of California, and National Association of Charterboat Operator; and one recommendation is for Truth Aquatics.

1. Install interconnected fire detection systems in all spaces where passengers and crew have routine access, including dining areas, sleeping quarters, and lounges;
2. Install portable fire extinguishers on ''existing vessels'' so that they meet the same current regulatory requirements for ''new vessels'';
3. Develop safe handling procedures for the operation and storage of potentially hazardous items such as rechargeable batteries; and
4. Develop crew firefighting and emergency egress training.

In addition, vessels regulated under Subchapters K and T that are not ferries and have overnight accommodations for passengers must also:
1. Have two unobstructed means of escape that are not located directly above, or dependent on, a berth;
2. Ensure that means of escape arrangements onboard ''existing vessels'' meet the same current regulatory requirements outlined for ''new vessels'';
3. Install and use a monitoring device to ensure the wakefulness of the required night watchmen;
4. Conduct passenger emergency egress drills; and
5. Post a passenger safety bill (that includes an emergency egress plan) in passenger accommodation spaces.

Table 1, ''Summary of Changes and 46 CFR Subchapters and Sections Affected'' provides a list of 11 categories of changes, as well as summaries of the changes, and a list of the affected subchapters and sections. After the table, we provide a detailed explanation of the changes in each category.

TABLE 1—SUMMARY OF CHANGES AND 46 CFR SUBCHAPTER AND SECTIONS AFFECTED

Category or equipment	Changes made	Affected 46 CFR subchapters and sections
Applicability and Definitions	1. Defines applicable vessels subject to regulatory change. 2. Adds definitions for ''*Listed*'' and for ''*Nationally recognized testing laboratory* or *NRTL*''.	Subchapter K: §§ 114.110(e), 114.110(f), and 116.115(c). Subchapter T: §§ 175.110(c), 175.110(d), 177.115(c), 175.400.
Editorial	Updates paragraph numbering resulting from insertion of new regulatory text.	Subchapter K: §§ 116.500(p),(q), and (r), 118.400(e),(f),(g),(h), and (i), 122.410(a), 122.420(c) and (d), and 122.515(c). Subchapter T: §§ 177.500(o),(p), and (q), 181.450(a)(3) and(4), 185.410(a), and 185.420(c) and (d).
Watchkeeping	Adds requirement for use of night watch monitoring device.	Subchapter K: § 122.410(b). Subchapter T: § 185.410(b).
Fire Detection	Updates requirements for type and location of interconnected fire detection systems.	Subchapter K: § 118.400(d). Subchapter T: §§ 181.405(c), 181.450(a)(1) and (a)(2), and 181.450(b).
Fire Suppression	Requires affected existing vessels to conform with current fire suppression regulations outlined in §§ 118.500 and 181.500.	Subchapter K: § 114.110(e). Subchapter T: § 175.110(c).
Training	Adds training requirement to enhance crews' firefighting capabilities.	Subchapter K: § 122.420(b). Subchapter T: § 185.420(b).
Egress	1. Adds requirements for master to conduct emergency egress drills. 2. Adds and updates requirements for posting Passenger Safety Bills.	Subchapter K: §§ 122.507 and 122.515. Subchapter T: §§ 185.507 and 185.515.
Construction and Arrangement	1. Requires vessels with overnight accommodations for passengers to conform to current regulations for means of escape construction and arrangement. 2. Adds requirements preventing berths to aid in means of escape.	Subchapter K: §§ 116.115(c) and 116.500(o). Subchapter T: §§ 177.115(c) and 177.500(n).
Hazardous items	Adds requirements for handling, storing, and operating potentially hazardous items.	Subchapter K: § 122.364. Subchapter T: § 185.364.
Implementation	Outlines implementation schedule for affected operators to implement regulatory requirements.	Subchapter K: § 114.110(g). Subchapter T: § 175.110(e).

Applicability and Definitions

The statute defines ''covered small passenger vessel,'' but, because the term ''cover(ed)'' is utilized already throughout Subchapters T and K to mean something unrelated, utilizing ''covered small passenger vessel'' could be misleading. Instead, the interim rule adds statements to the applicability sections in 46 CFR Subchapters K (§ 114.110) and T (§ 175.110) to identify the types of SPVs that must meet the new requirements. These statements of applicability capture all the ''covered small passenger vessels'' identified in the statute. For each applicability statement, we include a list of the specific regulatory sections that those types of vessels must comply with.

In accordance with the definition of covered SPVs in 46 U.S.C. 3306(n)(5), a vessel to which Subchapter K or T applies, irrespective of build date, must meet the listed general fire safety requirements if it is not a ferry; and (1) has overnight accommodations for passengers; or (2) is operating on a Coastwise or Oceans route. The fire safety requirements in this interim rule are substantively the same in each Subchapter. The general fire safety requirements are listed in §§ 118.400(d), 118.500, 122.364, and 122.420(b) for vessels regulated under Subchapter K and in §§ 181.405, 181.450, 181.500, 185.364, and 185.420(b) for vessels regulated under Subchapter T.

In addition to the general requirements, SPVs that have overnight accommodations for passengers will be required to meet additional fire safety requirements, as mandated by 46 U.S.C. 3306(n)(3)(B). For Subchapter K, SPVs with overnight accommodations for passengers, irrespective of build date, will be required to meet the additional requirements in revised §§ 116.115(c), 116.500(o), 122.410(b), 122.507, and 122.515. SPVs with overnight accommodations for passengers,

irrespective of build date, regulated under Subchapter T will have to meet the additional requirements in revised §§ 177.115(c), 177.500(n), 185.410(b), 185.507, and 185.515. These additional requirements are discussed later in this preamble, and are substantively the same in each subchapter.

Section 3306(n)(5)(B) states that the regulations do not apply to ferries or fishing vessels as those terms are defined in 46 U.S.C. 2101. As such, the new requirements implemented by this interim rule do not apply to ferries or fishing vessels. Under the statutory authorities and this interim rule, SPVs inspected under Subchapters K or T engaged in passenger vessel operations on a fishing excursion does not meet the definition of a ''fishing vessel'' in 46 U.S.C. 2101.

This interim rule also adds definitions to Subchapter T for the terms ''listed'' and ''Nationally recognized testing laboratory or NRTL.'' Both definitions will apply to the new requirements in § 181.450 for interconnected fire detection and alarm systems. In that section, we require an interconnected detection and alarm system to consist of multiple-station smoke detectors listed by an NRTL, or independent laboratory accepted by the Commandant. The definition of ''listed'' would help the reader identify what types of materials or equipment are acceptable under the regulations. The definition of ''NRTL'' will help the reader identify the organization as one that is recognized by the Occupational Safety and Health Administration.

Editorial

This interim rule makes several editorial changes to update paragraph numbering from the addition of new regulatory text. All affected paragraphs that have been redesignated by this interim rule are listed in Table 1 of this preamble, ''Summary of Changes and 46 CFR Subchapters and Sections Affected.'' These editorial changes have no substantive impact on the public or affected owners or operators of SPVs.

Watchkeeping

Existing regulations in 46 CFR 122.410 and 185.410 require an owner of a vessel carrying overnight passengers to have a suitable number of members of the crew patrol throughout the vessel during nighttime. Under 46 U.S.C. 3306(n)(3)(A)(iii), we must issue requirements for the installation and use of monitoring device(s) to ensure the wakefulness of the required night watch for SPVs with overnight accommodations for passengers. Sections 122.410 and 185.410 already require these vessels to have a suitable number of watchmen patrol throughout the vessel during the nighttime. The purpose of having a required night watch is to always have someone monitoring the safety and security of the vessel, who can alert the crew and passengers if there are any emergencies on board, such as fire, flooding, vessel collisions, or other hazards.

In new paragraphs 122.410(b) and 185.410(b), this interim rule requires the following for operators of vessels regulated by Subchapter T or K that have overnight accommodations for passengers. Vessels already in service must submit plans to the cognizant OCMI, in accordance with existing §§ 115.700 or §§ 176.700, for the installation and use of monitoring device(s) to ensure the wakefulness of the watchmen. Vessels with a keel laid date after March 28, 2022, must include plans for the monitoring device(s) within the plan submissions required in §§ 116.202 or 177.202. The Coast Guard will work with the vessel operators to determine a reasonable implementation schedule once the plans are accepted. This plan submission requirement will be effective 90 days after publication of this interim rule. The main goal for requiring use and installation of the monitoring device is to ensure the required watchmen stay awake while monitoring the vessel for emergencies.

The monitoring devices must also satisfy the following three requirements, which we have incorporated into the regulatory text. First, the monitoring devices must alert the crew in the case of an unresponsive watchstander. This requirement will ensure that, if a watchman becomes unresponsive, the crew will be alerted to check on the unresponsive watchman and provide a continuous safety watch throughout the night. Second, the monitoring device must remain operable throughout the nighttime watch, to coincide with the required patrol in §§ 122.410(a) and 185.410(a), which requires ''watchmen patrol throughout the vessel during the nighttime.'' Third, the monitoring device(s) must be arranged to ensure proper coverage of the passenger accommodation spaces, common areas, and spaces with potential fire hazards. We are requiring the device(s) be arranged with proper coverage around the vessel to ensure that those assigned with a watchkeeping responsibility remain alert while conducting frequent rounds of the vessel.

Per existing §§ 115.800(a) and 176.800(a), ''Inspection standards'', the cognizant OCMI may inspect the vessel's monitoring devices for compliance with the subchapter and, where the standard is not set by these updated regulations, in accordance with standards acceptable to the cognizant OCMI as good marine practice.

For implementing the monitoring device(s) requirement, we considered requiring systems similar to the International Electrotechnical Commission standard, IEC 62616, ''Maritime navigation and radio communication equipment and systems—Bridge navigational watch alarm system (BNWAS).'' The IEC 62616 standard specifies the minimum performance requirements, technical characteristics, methods of testing, and required test results for a BNWAS, as required by the International Convention for the Safety of Life as Sea (SOLAS). SOLAS regulation V/19.2.2.3 requires that BNWAS must be in operation whenever the ship is underway at sea. The BNWAS monitors bridge activity and detects operator disability that could lead to marine accidents. According to the IEC 62616 standard, the system monitors the awareness of the watchman. If they become incapable of performing their watch duties, a series of indications and alarms alert first the watchman and then, if they are not responding, alert the Master or another qualified watchman. Under IEC 62616, the BNWAS may be integrated into other equipment, such as radar or Electronic Chart Display and Information System, etc. A BNWAS is just one example of a device that would satisfy the requirements of §§ 122.410(b) and 185.410(b). Further, systems such as a personnel alarm, as required by 46 CFR 62.50–20(b) for vessels regulated under Subchapter F, would also be considered as meeting the requirements of §§ 122.410(b) and 185.410(b). These two systems are just examples, and are not intended as an all-inclusive list of devices that could satisfy the requirements of §§ 122.410(b) and 185.410(b). However, for the purpose of this interim rule, we are initially allowing operators the flexibility to choose a system that works for them in meeting the requirements set forth in 122.410(b) and 185.410(b), subject to cognizant OCMI or Marine Safety Center approval. We welcome comments providing information as to the types of wakefulness monitoring systems or procedures that are preferable or already in use by these vessels, if any.

Fire Detection

Title 46 CFR 181.450(c) lists the requirements for independent modular smoke detecting units in overnight accommodation spaces on a vessel. To align with the requirements of 46 U.S.C.

3306(n)(3)(A)(ii), vessels regulated by Subchapter T or K that have overnight accommodations for passengers or operate on a Coastwise or Oceans route, irrespective of build date, must now have interconnected fire detection systems.

The text in 46 U.S.C. 3306(b)(3)(A)(ii) requires interconnected fire detection equipment ''in all areas on board the vessel where passengers and crew have access, including dining areas, sleeping quarters, and lounges.'' The Coast Guard uses the term ''interconnected fire detection systems'' because it is not likely or logical that the fire detection equipment will be interconnected; it is the system that is interconnected. This is a nomenclature change we made to be more precise with the language used in the regulations. We have interpreted the statutory language, ''all areas where passengers and crew have access'' to include enclosed spaces such as accommodation spaces and machinery spaces that would be routinely occupied by passengers or crew. While the statute says, ''all areas on board the vessel where passengers and crew have access . . .'' the Coast Guard does not interpret this to mean only spaces where crew and passengers both have access; we interpret this to mean spaces where either have access. Otherwise, machinery spaces and crew kitchens with heat sources and fire risks would not be included in the requirement. That interpretation would be inconsistent with the intent of the 2020 CGAA, to have the interconnected fire detection systems in all areas onboard.

This interim rule does not require interconnected fire detection systems on weatherdecks because fire detection equipment is not effective above decks where there may be no ceilings and smoke disperses before it can be detected. In addition, we do not include small spaces that open to spaces with fire detection equipment, such as closets, in the meaning of ''areas where passengers and crew have routine access,'' where it is impractical or there are no potential heat sources to justify requiring an interconnected fire detection system therein.

The regulations in §§ 118.400(d) and 181.405(c) will now require an interconnected fire detection system that meets the existing requirements in § 181.450 in all enclosed areas to which passengers and crew have routine access, including accommodation spaces and machinery spaces. Now that the statute requires all SPV fire detection systems to be interconnected, we changed the type of the detection system described in § 181.450 from ''Independent modular smoke detecting units'' to ''Interconnected fire detection system''. Section 181.450 will continue to require that the fire detection system used by the vessel must be listed by an NRTL or independent laboratory, as type-approved to meet Underwriter Laboratories (UL) standard UL 217, ''Single and Multiple Station Smoke Detectors,'' already incorporated by reference in § 175.600 and 181.450.

In Subchapter K's interconnected fire detection system requirements, in new § 118.400(d), we opt to cross-reference the existing Subchapter T standards in § 181.450 that apply to interconnected fire detection systems, rather than duplicating the standards in Subchapter K. All SPVs that either operate on a Coastwise or Oceans route or have overnight accommodations for passengers, irrespective of build date, must have an interconnected fire detection system that meets the requirements in § 181.450.

Fire Suppression

Existing §§ 118.500 and 181.500 list the requirements for number, type, and location of portable fire extinguishers applicable to ''new vessels'' (defined in §§ 114.400 and 175.400). These sections list the minimum number of fire extinguishers a vessel must have and also indicate that the Officer in Charge, Marine Inspection (OCMI) may require more than the minimum number listed. Paragraph (n)(3)(A)(vii) of 46 U.S.C. 3306 requires the Coast Guard to issue regulations for increased fire suppression systems (including additional fire extinguishers) in unmanned areas with machinery, or areas with other potential heat sources. Sections 118.115 and 181.115 previously allowed ''existing vessels'' (defined in §§ 114.400 and 175.400) to comply with the fire protection regulations that were applicable to the vessel on March 10, 1996.

This interim rule requires all vessels regulated by Subchapter T or K that have overnight accommodations for passengers or are operating on a Coastwise or Oceans route, regardless of build date, to comply with the portable fire extinguisher regulations in §§ 118.500 or 181.500. The new applicability paragraphs §§ 114.110(e) and 175.110(c) indicate the specific regulations that these SPVs must meet, including the fire extinguisher regulations in §§ 118.500 or 181.500. These regulations were previously only applicable to ''new vessels.'' This change will directly affect ''existing vessels'' that previously complied with portable fire extinguisher regulations applicable to the vessel on March 10, 1996, but do not meet the regulation standards for ''new vessels.'' All SPVs regulated under Subchapters T and K that have overnight accommodations for passengers or are operating on a Coastwise or Oceans route will be required to comply with the portable fire extinguisher minimum numbers and type requirements in §§ 118.500 or 181.500 no later than 1 year after publication of this interim rule. The Coast Guard invites public comment to determine if requirements for additional portable fire extinguishers beyond what is currently required in §§ 118.500 or 181.500 should be required to facilitate proper fire protection.

Additionally, these SPVs will be subject to the cognizant OCMI's discretion in requiring additional portable fire extinguishers. In requiring additional portable fire extinguishers, the OCMI considers multiple factors, including such vessel characteristics as the size, passenger capacity, egress plans, and layout. This OCMI discretion already exists in 118.500(a) and 181.500(a). Therefore, we expect OCMIs to use the same criteria they apply to new vessels to existing vessels in determining an acceptable minimum amount of fire extinguishers in the spaces listed. The fire extinguisher requirements in §§ 118.500 and 181.500 cover all types of areas on the vessel, including minimum fire extinguisher requirements for unmanned areas with machinery, and areas with potential heat sources, as required by the statute.

In this interim rule, the Coast Guard considered requiring fixed firefighting systems to address the requirements of 46 U.S.C. 3306(n), but decided instead to make the standards for the number, type, and location of portable extinguishers onboard new vessels applicable to both new and existing vessels. When the Coast Guard revised the regulations for small passenger vessels in 1996, the requirements for fixed fire suppression systems were retroactively applied to existing vessels of combustible construction (See 61 FR 864, Jan. 10, 1996). These higher risk vessels have been required to install fixed suppression systems since March 1999. However, under the 1996 regulation, existing vessels were not required to comply with requirements for the number, type, and location of portable extinguishers. At present, there is insufficient data to justify requiring the additional cost and complexity of fixed systems on existing vessels of non-combustible construction. Instead, under the interim rule, the Coast Guard is requiring existing vessels to meet the current requirements for portable fire extinguishers, which meets the intent of 46 U.S.C. 3306(n). At the same time, the

interim final rule will allow for public comment regarding requirements for portable and fixed fire suppression systems onboard these vessels.

Training

Currently, SPVs are required to conduct crew firefighting drills and training in accordance with §§ 122.524 and 185.524. Per the mandate in 46 U.S.C. 3306(n)(3)(A)(i), this interim rule adds additional crew firefighting training requirements for vessels regulated by Subchapter T or K that have overnight accommodations for passengers or are operating on a Coastwise or Oceans route. These additional training requirements will promote crew member firefighting proficiency, while requiring regular egress training for vessel crew members.

In new paragraphs 122.420(b) and 185.420(b), this interim rule adds required crew training in the use and location of firefighting equipment and general firefighting knowledge, including a list of knowledge and training aspects that must be covered. Additionally, this interim rule adds a requirement to conduct emergency egress training for all members of the crew, to be conducted at least monthly while such members are employed on board the vessel, and each time someone joins the crew.

The new provisions in §§ 122.420(b) and 185.420(b) will also cross-reference the existing requirements for the vessel master or operator to conduct the firefighting drills and training in §§ 122.524 and 185.524, respectively, including identifying fire location and fire type. The additional general firefighting knowledge requirements in §§ 122.524 and 185.524 already apply to all vessels regulated under Subchapter K and Subchapter T, respectively. The purpose of adding these cross references to §§ 122.420(b) and 185.420(b) is to clearly specify in one place all the firefighting crew training requirements for SPVs that have overnight accommodations for passengers or are operating on a Coastwise or Oceans route.

Egress

46 U.S.C. 3306(n)(3)(A)(vii) requires regulations for conducting passenger emergency egress drills prior to the vessel beginning each excursion. New §§ 122.507 and 185.507 of this interim rule require owners or operators of SPVs that have overnight accommodations for passengers to conduct emergency egress drills with the new passengers prior to the vessel getting underway. If the vessel does not get underway, and if passengers do not remain overnight on the vessel, the vessel operator would not be required to complete the passenger emergency egress drills. The statute requires the egress drills be performed before the vessel begins an ''excursion,'' which we have interpreted to mean anytime a vessel gets underway, or anytime passengers remain overnight on the vessel. Per this definition, a vessel operator that has passengers remain onboard overnight is required to conduct the passenger emergency egress drills, regardless if the vessel leaves the pier. Where vessels with overnight passengers remain pierside for various reasons, such as inclement weather or as part of the normal practice, emergencies can still happen on these excursions. Requiring the emergency egress drills for vessels with overnight passengers that remain pierside supports Congress's safety intent of performing the passenger egress drills on these vessels.

For passengers assigned to an accommodation space, this interim rule requires the emergency egress drills must be performed from that assigned space. If passengers are not assigned an accommodation space, the emergency egress drill must be performed from another reasonable accommodation space, which the master of the vessel will have discretion to choose. We included this contingency for when passengers are not assigned accommodation space for situations where the vessel has overnight accommodation space for passengers but is not getting underway with passengers. In these cases, the master of the vessel is still required to perform an emergency egress drill with the passengers because the 46 U.S.C. 3306(n)(5) definition of ''covered small passenger vessel'' applies to any SPV that has overnight passenger accommodations on the vessel and does not distinguish whether or not they are actually used overnight by passengers.

Section 3306(n)(3)(A)(vii) requires the crew to conduct an egress drill from all areas where passengers have access. However, strict application of the statute would lead to an overly redundant and burdensome process, with multiple drills being conducted from every accessible space on the vessel, and only a nominal increase in safety. Instead, we will require passengers to undergo one emergency egress drill from their assigned accommodation space, or, if not assigned an accommodation space, from another reasonable accommodation space chosen by the vessel master.

The emergency egress drills are a supplement to any applicable passenger safety requirements under 46 CFR parts 122 and 185 or SOLAS. In some cases, the emergency egress drill can be done concurrently with other required safety drills, as long as the passengers perform the emergency egress drill starting from the passenger's assigned accommodation spaces before beginning an excursion with new passengers. Most relevant, §§ 122.506(e) and 185.506(e) require SPVs on a voyage of more than 24 hours duration request that passengers don life jackets and go to the appropriate embarkation station during the safety orientation. A vessel operator could satisfy §§ 122.506(e) or 185.506(e) and the new emergency egress drill requirement by performing the emergency egress drill from the passenger's assigned overnight accommodation space, meeting at the embarkation station, and donning life jackets. This emergency egress drill must be conducted before the vessel begins an excursion with new passengers.

Paragraphs 3306(n)(3)(A)(viii) & (B) require providing passengers a copy of the emergency egress plan for the vessel on vessels that have overnight accommodation spaces for passengers. In Subchapters K and T, the Coast Guard refers to these plans as passenger safety bills. This interim rule requires passenger safety bills to be posted in each cabin or stateroom, and in passenger accommodation spaces. Passenger safety bills must include the following information: (1) The embarkation station and the number and location of survival craft to which each passenger is assigned, if applicable; (2) the fire and emergency signal and the abandon ship signal; (3) the essential action that must be taken in an emergency; and (4) the location of immersion suits and illustrated instructions on the method of donning the suits, if immersion suits are provided. The Coast Guard determined that including this emergency egress information will increase the passenger safety bill's usefulness to passengers during an emergency.

These passenger safety bill requirements will be in § 122.515 and new § 185.515. Previously, passenger safety bill requirements in § 122.515 only applied to vessels more than 65 feet with more than 49 overnight passengers. The requirements in § 122.515 will now apply to all vessels regulated under Subchapter K with overnight accommodations spaces for passengers, regardless of length of vessel or number of overnight passengers.

The Coast Guard considered requiring masters of affected vessels to distribute copies of passenger safety bills to passengers. We did not choose this option as it is unrealistic to expect

passengers to have the safety bills in their possession at all times in case of an emergency. Posting the passenger safety bills in accommodation spaces and staterooms ensures the emergency egress plans are available for viewing from multiple places on the vessel in an emergency.

Construction and Arrangement

The regulations for construction and arrangement in 46 CFR parts 116 and 175 are currently applicable to ''new vessels'' (defined in §§ 114.400 and 175.400). ''Existing vessels'' (also defined in §§ 114.400 and 175.400) have the opportunity to comply with regulations that were applicable on March 10, 1996. Section 3306(n)(3)(A)(v) of 46 U.S.C. requires SPVs with overnight accommodations for passengers to have two independent avenues of escape from general areas accessible to passengers. New applicability provisions in §§ 116.115(c) and 177.115(c) will require vessels regulated by Subchapter T or K that have overnight accommodations for passengers, regardless of build date, to comply with the requirements for means of escape in §§ 116.500 and 177.500. Requiring compliance with §§ 116.500 and 177.500 will ensure that all existing vessels with overnight accommodations for passengers will maintain at least two independent means of escape that allow for free and unobstructed egress from any point in a vessel to an embarkation station for SPVs regulated under Subchapter T, or to an embarkation station or area of refuge for SPVs regulated under Subchapter K.

Specifically, §§ 116.500(b) and 177.500(b) require two means of escape that must be widely separated and, if possible, at opposite ends or sides of the space to minimize the possibility of one incident blocking both escapes. Although the terms ''if possible'' and ''minimize the possibility'' provide a level of ambiguity to the regulations, the notion of having two means of escape widely separated at opposite ends of the space, where a blockage of one will not result in the blockage of both escapes, is enforced strictly. The term ''if possible'' in relation to placement of the means of escape provides a level of discretion to the Coast Guard to allow for the two independent means of escape to exist in the same space without being on absolute opposite ends of the space. However, the Coast Guard will ensure, in its judgement, that the means of escape are placed as widely apart as possible to minimize the possibility that one incident could block both means of escape. Current regulations under Subchapter T define a ''means of escape'' as ''a continuous and unobstructed way of exit travel from any point in a vessel to an embarkation station.'' For vessels inspected under Subchapter K, a ''means of escape'' is ''a continuous and unobstructed way of exit travel from any point in a vessel to an embarkation station or area of refuge.'' (*See* 46 CFR 114.400 and 175.400). Regardless of how widely spaced the means of escape are from each other in a single space, the Coast Guard will ensure there are two independent means of escape that prevent one incident blocking both means of escape.

Additionally, this interim rule will add a new provision prohibiting avenues of escape that are located directly above, or dependent on, a berth for vessels with overnight accommodations for passengers. Section 3306(n)(3)(A)(v)(III) mandates that the required two independent avenues of escape and the door, hatch, or scuttle are not located directly above or dependent on a berth. This mandated requirement is implemented in revised §§ 116.500(o) and 177.500(n) only for vessels with overnight accommodations for passengers.

Hazardous Items

Under 46 U.S.C. 3306(n)(3)(A)(vi), all vessels regulated by Subchapters K or T that have overnight accommodations for passengers, or are operating on a Coastwise or Oceans route, will be required to take extra precautions in handling, storing, and operating flammable items such as rechargeable batteries.[3] New §§ 122.364 and 185.364 require potentially hazardous items used for commercial purposes to be handled, stored, and operated in a way that mitigates the risk of hazardous conditions. In addition, operators should read the Coast Guard's Office of Commercial Vessel Compliance (CG–CVC) Policy Letter 20–03, ''Carriage of Lithium-Ion Batteries on Small Passenger Vessels,'' issued on October 29, 2020 (or any subsequent versions), to better understand how to identify signs of damage to lithium ion batteries, how to extinguish small lithium-ion battery fires, and how to avoid unsafe practices or improper installations onboard.[4] A copy of the Policy Letter 20–03 will be posted to the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

Implementation

The Coast Guard considered implementation schedules while balancing expected or potential impacts and vessel and passenger safety concerns. In the Subchapters K and T applicability sections, 114.110(g) and 175.110(e), we list the dates of when each regulatory requirement must be implemented. These dates are the earliest that the Coast Guard would enforce the requirements. We opt for a staggered implementation schedule, where the more extensive changes are given more time to implement, and the simpler changes are given 90 days to implement.

The new requirements for means of escape in §§ 116.115(c), 116.500(o), 177.115(c), and 177.500(n) are deemed the most logistically challenging. Relevant vessel owners could expect to allocate time and resources for making appropriate vessel conversions. Vessel owners may need to schedule a drydocking period with a boatyard to conduct conversions necessary to meet the means of escape requirements in these sections. Therefore, we allow vessel owners 2 years to implement those requirements; that is, by December 27, 2023.

The regulatory changes for fire protection equipment in 46 CFR parts 118 and 181 will require equipment to be procured and installed onboard. The Coast Guard recognizes that required equipment may not be readily available, so we have allowed vessel owners 1 year, until December 27, 2022, to implement the requirements in §§ 118.400(d), 118.500, 181.405, 181.450, and 181.500.

Vessel owners will have 90 days, until March 28, 2022, to implement the remaining requirements of this interim rule. These requirements include those listed in §§ 122.364, 122.420(b), 116.115(c), 122.410(b), 122.507, 122.515, 185.364, 185.410(b), 185.420(b), 185.507, and 185.515.

Lastly, §§ 122.507(b), 185.507(b), and 185.515(a), and the addition of a paragraph to § 122.515, which contain collections of information that have not yet been approved by OMB, are delayed indefinitely. These sections are related to the requirements for posting a passenger safety bill in accommodation spaces, recording passenger egress drills, and recording crew firefighting and emergency egress training. The Coast Guard will publish a document in the **Federal Register** announcing the effective dates of those sections if OMB

[3] As required by 46 U.S.C. 3306(n)(3)(A)(vi).

[4] A copy is available in the docket for this interim rule and at the following website: *https://www.dco.uscg.mil/Portals/9/DCO%20Documents/5p/CG-5PC/CG-CVC/Policy%20Letters/2020/CVC%20PL%2020-03_CARRIAGE%20OF%20LITHIUM-ION%20BATTERIES%20ON%20SMALL%20PASSENGER%20VESSELS.pdf.*

approves the new collections of information.

V. Regulatory Analyses

Paragraph (n)(4)(B) of 46 U.S.C. 3306 exempts the requirements in this interim rule from the economic analysis requirements in the Regulatory Flexibility Act and Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review). The Office of Management and Budget (OMB) has not reviewed this rule under section 3(f) of Executive Order 12866 because this interim rule is exempt from the requirements of Executive Order 12866.

This interim rule will impose a cost to the SPV industry, much of which is made up of small businesses. While the Coast Guard did not conduct a benefit cost analysis, the Coast Guard recognizes that there may be impacts to small business. There will be a cost burden to update fire and smoke detection equipment and to add additional independent avenues of escape (for instance, egress) on many SPVs, with a potential associated loss of passenger capacity on some SPVs. Additional costs will be associated with crew training and competency, passenger egress drills, monitoring devices to ensure wakefulness of the night watch, and flammable item storage. The Coast Guard will consider all cost-related public comments at the final rule phase and not for this interim final rule.

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on these statutes or Executive orders.

A. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, we offer to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking. 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.

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).

B. Collection of Information

This interim rule calls for a change to an existing collection of information under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520. The relevant collection of information is titled ''Small Passenger Vessels—Title 46 CFR Subchapters K and T,'' which is assigned OMB Control Number 1625–0057. The Coast Guard uses the information in this collection to ensure compliance with Subchapter K and T regulations for the safety, design, construction, alteration, repair and operation of small passenger vessels.

As defined in 5 CFR 1320.3(c), ''collection of information'' comprises reporting, recordkeeping, monitoring, posting, labeling, and other similar actions. The title and description of the information collections, a description of those who must collect the information, and an estimate of the total annual burden follow. The estimate covers the time for reviewing instructions, searching existing sources of data, gathering and maintaining the data needed, and completing and reviewing the collection.

Title: Small Passenger Vessels—Title 46 CFR Subchapters K and T.

OMB Control Number: 1625–0057.

Summary of the Collection of Information: The information requirements are necessary for the proper administration and enforcement of the safety of applicable SPVs affected by this interim rule. The new requirements of this interim rule affect SPVs (under 100 gross tons) that carry more than six passengers and have overnight accommodations for passengers or operate on a coastwise or oceans route. The Coast Guard will require the operators of these vessels to: (1) Post copies of the passenger safety bill for all passengers in all passenger staterooms and cabins and passenger accommodation spaces; (2) log the occurrence of passenger emergency egress drills; and (3) log the occurrence of crew marine firefighting and emergency egress training. The interim rule requirement for vessel operators of SPVs with overnight accommodations for passengers to submit plans to the USCG for use and installation of night watchmen monitoring devices would also increase the burden estimates for the existing collections covered by plan approval sections §§ 115.700, 116.202, 176.700 and 177.202.

Need for Information: Under the authority of 46 U.S.C. 3305 and 3306, the Coast Guard is prescribing regulations for the design, construction, alteration, repair and operation of SPVs to secure the safety of individuals and property on board. The Coast Guard must issue interim fire safety requirements for these vessels per 46 U.S.C. 3306(n), requiring masters of SPVs to provide passengers copies of emergency egress plans and to conduct passenger emergency egress drills before every excursion, and conduct crew marine firefighting and emergency egress trainings monthly and every time a new crewmember joins the crew. Plan approvals for the night watchmen monitoring devices is needed to ensure the devices will perform adequately to ensure the wakefulness of the night watch.

Proposed Use of Information: The Coast Guard is requiring vessel operators to post copies of the passenger safety bill in all passenger staterooms and passenger accommodation spaces for the passengers' access and use before and during an emergency. Additionally, the requirement for vessel operators to log the occurrence of passenger emergency egress drills and crew firefighting and emergency egress training will be used by the Coast Guard to inspect vessel operators' compliance with the requirements. The plans for the night watch monitoring devices will be used to ensure compliance with the requirement to installation and use of the devices meet the minimum standards in the regulations.

Description of the Respondents: Owners and operators of SPVs (under 100 gross tons) that carry more than six passengers with overnight accommodations for passengers.

Number of Respondents: The current OMB-approved number of respondents remains unchanged.

Frequency of Response: The log entry for passenger egress drills must be completed prior to every excursion. The log entry for the crew firefighting and emergency egress training is expected to occur once a month and every time a new crew member joins the crew. The posting of the passenger bill will be a one-time posting requirement per vessel. The plan submission for the night watch monitoring devices will be a one-time submission requirement per vessel.

Burden of Response: The burden of response varies per activity. The log entry at the completion of a passenger egress drill takes 2 minutes to complete prior to every excursion. The log entry at the completion of the crew firefighting training takes 2 minutes to complete and is expected to occur an average of 18 times per year, per

applicable vessel. The posting of a passenger safety bill takes 1 minute per activity with 10 activities per Subchapter K vessel and 6 activities per Subchapter T vessel, and we expect each vessel to post passenger safety bills only once. The submission of a vessel plan takes 30 minutes per activity with an estimated 370 submissions.

Estimate of Total Annual Burden: The crew emergency egress training will increase the annual burden by 676 hours. The new passenger egress drills will increase the annual burden by 611 hours. The posting of additional passenger safety bills will increase the annual burden by 46 hours. The one-time submission of the night watch monitoring device plan submission will increase the annual burden by 185 hours. This rulemaking will increase the estimated annual burden by 1,518 hours.

As required by 44 U.S.C. 3507(d) and 5 CFR 1320.10, we will submit a copy of this interim rule to OMB for its review of the collection of information.

We are soliciting comments on the revisions to the collection of information. Comments may be submitted in accordance with the Public Participation and Request for Comments section in this preamble.

You are not required to respond to a collection of information unless it displays a currently valid OMB control number. OMB has not yet completed its review of this updated collection. Therefore, we are not making §§ 122.507(b), a new paragraph in 122.515, 185.507(b), and 185.515(a) effective until OMB completes its action on our revised information collection request. We will publish a **Federal Register** document describing OMB's action and, if OMB grants approval, notifying you when §§ 122.507(b), the new paragraph in 122.515, 185.507(b), and 185.515(a) take effect.

C. Federalism

A rule has implications for federalism under Executive Order 13132 (Federalism) if it has a substantial direct effect on 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 interim rule under Executive Order 13132 and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132. Our analysis follows.

It is well settled that States may not regulate in categories reserved for regulation by the Coast Guard. It is also well settled that all of the categories covered in 46 U.S.C. 3306, (design, construction, alteration, repair, maintenance, operation, equipping), in which Congress intended the Coast Guard to be the sole source of a vessel's obligations, are within the field foreclosed from regulation by the States. *See* the Supreme Court's decision in *United States* v. *Locke* and *Intertanko* v. *Locke,* 529 U.S. 89, 120 S.Ct. 1135 (2000). This interim rule implements mandatory fire safety requirements for SPVs prescribed by 46 U.S.C. 3306(n). Therefore, because the States may not regulate within these categories, this rule is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

While it is well settled that States may not regulate in categories in which Congress intended the Coast Guard to be the sole source of a vessel's obligations, the Coast Guard recognizes the key role that State and local governments may have in making regulatory determinations. Additionally, for rules with federalism implications and preemptive effect, Executive Order 13132 specifically directs agencies to consult with State and local governments during the rulemaking process. If you believe this rule has implications for federalism under Executive Order 13132, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

D. Unfunded Mandates

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. The Coast Guard discusses the requirements and some of the implications of this interim rule elsewhere in the preamble. This interim rule is exempt from economic analysis requirements in the Regulatory Flexibility Act and Executive Orders 12866 and 13563. Hence, this rulemaking does not include a regulatory analysis. Additionally, the interim requirements implemented by this rule are required by statute and are not discretionary.

E. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630 (Governmental Actions and Interference with Constitutionally Protected Property Rights).

F. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988 (Civil Justice Reform) to minimize litigation, eliminate ambiguity, and reduce burden.

G. Protection of Children

We have analyzed this rule under Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks). This rule will not create an environmental risk to health or risk to safety that might disproportionately affect children.

H. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), because it will 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.

I. Energy Effects

We have analyzed this rule under Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use). We have determined that it is not a ''significant energy action'' under that order because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

J. Technical Standards and Incorporation by Reference

The National Technology Transfer and Advancement Act, codified as a note to 15 U.S.C. 272, directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (for example, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule uses one voluntary consensus standard, UL 217, ''Single and Multiple Station Smoke Detectors.'' The sections that reference this standard and the locations where this standard is available are listed in 46 CFR 175.600

and 181.450(a)(1). UL 217 is a standard for type-approved multiple-station smoke detectors, and is already incorporated by reference in these sections.

The Director of the Federal Register has approved the material in 46 CFR 181.450(a)(1) for incorporation by reference under 5 U.S.C. 552 and 1 CFR part 51. Copies of the material are available from the sources listed in 46 CFR 175.600.

Consistent with 1 CFR part 51 incorporation by reference provisions, this material is reasonably available. Interested persons have access to it through their normal course of business, may purchase it from the organization identified in 46 CFR 117.600, or may view a copy by means we have identified in that section.

K. Environment

We have analyzed this rule under Department of Homeland Security Management 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 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. 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. This rule is categorically excluded under paragraph L56 and L57of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev 1. Paragraph L56 pertains to regulations concerning the training, qualifying, licensing, and disciplining of maritime personnel and L57 pertains to regulations concerning manning, documentation, admeasurement, inspection, and equipping of vessels. This rule involves adding requirements such as fire detection and suppression systems, avenues of escape, egress drills, marine firefighting training, and the handling of flammable items such as rechargeable batteries.

VI. Public Participation and Request for Comments

The Coast Guard views public participation as essential to effective rulemaking, and will consider all comments and material received on this interim rule during the comment period. Your comment can help shape fire safety final rules for SPVs called for by 46 U.S.C. 3306(n). If you submit a comment, please include the docket number for this rule, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision Making Portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2021–0306 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this interim rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this interim rule as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. We review all comments received, but we will only post comments that address the topic of the interim rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Public meeting. We are not planning to hold a public meeting but will consider doing so if we determine from public comments that a meeting would be helpful. We would issue a separate **Federal Register** notice to announce the date, time, and location of such a meeting.

List of Subjects in 46 CFR Parts 114, 116, 118, 122, 175, 177, 181, and 185

46 CFR Part 114

Marine safety, Passenger vessels, Reporting and recordkeeping requirements.

46 CFR Part 116

Fire prevention, Marine safety, Passenger vessel, Seamen.

46 CFR Part 118

Fire prevention, Marine safety, Passenger vessels.

46 CFR Part 122

Marine safety, Passenger vessels, Penalties, Reporting and recordkeeping requirements.

46 CFR Part 175

Marine safety, Incorporation by reference, Passenger vessels, Reporting and recordkeeping requirements.

46 CFR Part 177

Marine safety, Passenger vessels, Reporting and recordkeeping requirements.

46 CFR Part 181

Fire prevention, Incorporation by reference, Marine safety, Passenger vessels.

46 CFR Part 185

Marine safety, Passenger vessels, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Coast Guard amends 46 CFR parts 114, 116, 118, 122, 175, 177, 181, and 185 as follows:

Title 46—Shipping

PART 114—GENERAL PROVISIONS

■ 1. The authority citation for part 114 is revised to read as follows:

Authority: 46 U.S.C. 2103, 3306, 3703; Pub. L. 103–206, 107 Stat. 2439; 49 U.S.C. App. 1804; DHS Delegation 00170.1, Revision No. 01.2, paragraph (II)(92)(a); § 114.900 also issued under 44 U.S.C. 3507.

■ 2. Amend § 114.110 by adding paragraphs (e) through (g) to read as follows:

§ 114.110 General applicability

* * * * *

(e) Irrespective of build date, a vessel to which this subchapter applies must meet 46 CFR 118.400(d), 118.500, 122.364, and 122.420(b) if it is not a ferry, and if it —

(1) Has overnight accommodations for passengers; or

(2) Is operating on a Coastwise or Oceans route.

(f) Irrespective of build date, a vessel to which this subchapter applies must meet 46 CFR 116.115(c), 116.500(o), 122.410(b), 122.507, and 122.515 if it is not a ferry, and has overnight accommodations for passengers.

(g) The requirements outlined in paragraphs (e) and (f) of this section must be met no later than March 28, 2022, except for:

(1) The requirements to implement 46 CFR 118.400(c) and 118.500r, which must be met no later than December 27, 2022; and

(2) The requirements to implement 46 CFR 116.115(c) and 116.500(o), which must be met no later than December 27, 2023.

PART 116—CONSTRUCTION AND ARRANGEMENT

■ 3. The authority citation for part 116 is revised to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277, DHS Delegation 00170.1, Revision No. 01.2, paragraph (II)(92)(a).

■ 4. Amend § 116.115 by adding paragraph (c) to read as follows:

§ 116.115 Applicability to existing vessels.

* * * * *

(c) Vessels described by 46 CFR 114.110(f) must comply with the regulations in § 116.500.

■ 5. Amend § 116.500 as follows:

■ a. Redesignate paragraphs (o) through (q) as (p) through (r), respectively; and

■ b. Add new paragraph (o).

The addition reads as follows:

§ 116.500 Means of escape.

* * * * *

(o) Vessels described by 46 CFR 114.110(f) must ensure that the two means of escape required in paragraph (b) of this section are unobstructed and not located directly above, or dependent on, a berth.

* * * * *

PART 118—FIRE PROTECTION EQUIPMENT

■ 6. The authority citation for part 118 is revised to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; DHS Delegation 00170.1, Revision No. 01.2, paragraph (II)(92)(a).

■ 7. Amend § 118.400 as follows:

■ a. Redesignate paragraphs (d) through (h) as (e) through (i), respectively; and

■ b. Add new paragraph (d).

The addition reads as follows:

§ 118.400 Where required.

* * * * *

(d) Vessels described by 46 CFR 114.110(e) must have an interconnected fire detection system in compliance with 46 CFR 181.450 installed in all enclosed areas where passengers and crew have routine access, including accommodation spaces and machinery spaces.

* * * * *

PART 122—OPERATIONS

■ 8. The authority citation for part 122 is revised to read as follows:

Authority: 46 U.S.C. 2103, 3306, 6101; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; DHS Delegation 00170.1, Revision No. 01.2, paragraph (II)(92)(a).

■ 9. Add § 122.364 to subpart C to read as follows:

§ 122.364 Use of potentially hazardous items for commercial purposes.

On vessels described by 46 CFR 114.110(e), flammable items not covered by the regulations of this subchapter, such as rechargeable batteries, including lithium ion batteries utilized for commercial purposes, must be handled, stored, and operated in a way that mitigates the risk of hazardous conditions.

■ 10. Amend § 122.410 as follows:

■ a. Redesignate the introductory text as paragraph (a); and

■ b. Add paragraph (b).

The addition reads as follows:

§ 122.410 Watchmen.

* * * * *

(b) Vessels described by 46 CFR 114.110(f) must submit plans to the cognizant OCMI, in accordance with 46 CFR 115.700, for the installation and use of monitoring device(s) to ensure the wakefulness of the watchmen required in paragraph (a) of this section. Vessels with a keel laid date after March 28, 2022, must include plans for the monitoring device(s) within the plan submissions required in 46 CFR 116.202. The Coast Guard will work with the vessel operators to determine a reasonable implementation schedule once the plans are accepted. The monitoring device(s) must:

(1) Ensure the wakefulness of the crew in the event that the watchman required in paragraph (a) of this section is unresponsive;

(2) Remain operable during the nighttime watch; and

(3) Be arranged to ensure proper coverage of the passenger accommodation spaces, common areas, and spaces with potential fire hazards.

■ 11. Amend § 122.420 as follows:

■ a. Redesignate paragraphs (b) and (c) as paragraphs (c) and (d);

■ b. Add new paragraph (b); and

■ c. In newly redesignated paragraph (c):

■ i. Add the text ‘‘, monthly,’’ after the word ‘‘initial’’; and

■ ii. Remove the text ‘‘paragraph (a)’’ and add in its place the text ‘‘paragraphs (a) and (b)’’.

The addition reads as follows:

§ 122.420 Crew training.

* * * * *

(b) For a vessel described by 46 CFR 114.100(e), the training program in paragraph (a) of this section must address firefighting proficiency and must include, but need not be limited to—

(1) Training in the use and location of firefighting equipment and general firefighting knowledge, including:

(i) Location of firefighting appliances and emergency escape routes;

(ii) Types and sources of ignition;

(iii) Flammable materials, fire hazards and spread of fire;

(iv) The need for constant vigilance;

(v) Actions to be taken on board;

(vi) Fire and smoke detection and automatic systems on board; and

(vii) Classification of fire and applicable extinguishing agents.

(2) The drills required by § 122.524, including fire location and fire type; and

(3) Emergency egress training for each member of the crew, to occur for all members of the crew—

(i) At least monthly while such members are employed on board the vessels; and

(ii) Each time a crew member joins the crew of such vessel.

* * * * *

■ 12. Add § 122.507 to read as follows:

§ 122.507 Passenger egress drills.

(a) The master of a vessel described by 46 CFR 114.110(f) must conduct passenger emergency egress drills from the passengers’ assigned overnight accommodation spaces prior to beginning an excursion with new passengers.

(1) If the passengers are not assigned an overnight accommodation space, the master of a vessel described by 46 CFR 114.110(f) must conduct passenger emergency egress drills from an accommodation space prior to beginning an excursion with new passengers.

(2) For the purposes of this section, excursion includes anytime the vessel gets underway, or anytime passengers remain overnight on the vessel.

(b) [Reserved]

■ 13. Delayed indefinitely, amend § 122.507 by adding paragraph (b) to read as follows:

§ 122.507 Passenger egress drills.

* * * * *

(b) Passenger egress drills must be logged or otherwise documented for review by the Coast Guard upon request. The drill entry must include the following information:

(1) Date and time of the drill; and

(2) Number of drill participants.

■ 14. Delayed indefinitely, amend § 122.515 as follows:

■ a. Redesignate paragraph (b) as paragraph (c); and

■ b. Add new paragraph (b).

The addition reads as follows:

§ 122.515 Passenger safety bill.

* * * * *

(b) For vessels described by 46 CFR 114.110(f), the master must post a passenger safety bill in each passenger cabin or stateroom and in passenger accommodation spaces.

* * * * *

PART 175—GENERAL PROVISIONS

■ 15. The authority citation for part 175 is revised to read as follows:

Authority: 46 U.S.C. 2103, 3205, 3306, 3703; Pub. L. 103–206, 107 Stat. 2439; 49 U.S.C. App. 1804; DHS Delegation 00170.1, Revision No. 01.2, paragraph (II)(92)(a); § 175.900 also issued under 44 U.S.C. 3507.

■ 16. Amend § 175.110 by adding paragraphs (c) through (e) to read as follows:

§ 175.110 General applicability.

* * * * *

(c) Irrespective of build date, a vessel to which this subchapter applies must meet 46 CFR 181.405, 181.450, 181.500, 185.364, and 185.420(b), if it is not a ferry, and if it—

(1) Has overnight accommodations for passengers; or

(2) Is operating on a Coastwise or Oceans route.

(d) Irrespective of build date, a vessel to which this subchapter applies must meet 46 CFR 177.115(c), 177.500(n), 185.410(b), 185.507, and 185.515, if it is not a ferry and has overnight accommodations for passengers.

(e) The requirements outlined in paragraphs (c) and (d) of this section must be met no later than March 28, 2022, except for:

(1) The requirements to implement 46 CFR 181.405, 181.450, and 181.500, which must be met no later than December 27, 2022; and

(2) The requirements to implement 46 CFR 177.115(c) and 177.500(n), which must be met no later than December 27, 2023.

■ 17. Amend § 175.400 by adding in alphabetical order definitions for ''Listed'' and ''Nationally recognized testing laboratory or NRTL'' to read as follows:

§ 175.400 Definitions of terms used in this subchapter.

* * * * *

Listed means equipment or materials included in a list published by an organization that is an accepted independent laboratory, as defined in 46 CFR 159.010, or a nationally recognized testing laboratory, as set forth in 29 CFR 1910.7, whose listing states that either the equipment or material meets appropriate designated standards.

* * * * *

Nationally recognized testing laboratory or *NRTL* means an organization that the Occupational Safety and Health Administration (OSHA) has recognized as meeting the requirements in 29 CFR 1910.7.

* * * * *

PART 177—CONSTRUCTION AND ARRANGEMENT

■ 18. The authority citation for part 177 is revised to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; DHS Delegation 00170.1, Revision No. 01.2, paragraph (II)(92)(a).

■ 19. Amend § 177.115 by adding paragraph (c) to read as follows:

§ 177.115 Applicability to existing vessels.

* * * * *

(c) Vessels described by 46 CFR 175.110(d) must comply with the regulations in § 177.500.

■ 20. Amend § 177.500 as follows:

■ a. Redesignate paragraphs (n) through (p) as paragraphs (o) through (q), respectively; and

■ b. Add new paragraph (n).

The addition reads as follows:

§ 177.500 Means of escape.

* * * * *

(n) Vessels described by 46 CFR 175.110(d) must ensure that the two means of escape required in paragraph (b) of this section are unobstructed and the door, hatch, or scuttle is not located directly above, or dependent on, a berth.

* * * * *

PART 181—FIRE PROTECTION EQUIPMENT

■ 21. The authority citation for part 181 is revised to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; DHS Delegation 00170.1, Revision No. 01.2, paragraph (II)(92)(a).

■ 22. Amend § 181.405 by revising paragraph (c) to read as follows:

§ 181.405 Spaces required to have fire detection systems.

* * * * *

(c) Vessels described by 46 CFR 175.110(c) must have an interconnected fire detection system in compliance with § 181.450 installed in all enclosed areas where passengers and crew have routine access, including accommodation spaces and machinery spaces.

* * * * *

■ 23. Revise § 181.450 to read as follows:

§ 181.450 Interconnected detection and alarm system.

(a) An interconnected detection and alarm system must:

(1) Consist of multiple-station smoke detectors listed by an NRTL, or independent laboratory accepted by the Commandant according to 46 CFR subpart 159.010, as meeting UL 217 (incorporated by reference, see 46 CFR 175.600);

(2) Be installed such that the actuation of alarm in one area results in both audible and visual alarms in all areas required by 46 CFR 181.405(c) or 118.400(d) to be protected by the interconnected detection and alarm system;

(3) Contain an independent power source; and

(4) Alarm on low power.

(b) A fire detection and alarm system of an approved type installed in accordance with 46 CFR part 76 would satisfy the requirements of this section.

PART 185—OPERATIONS

■ 24. The authority citation for part 185 is revised to read as follows:

Authority: 46 U.S.C. 2103, 3306, 6101; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; DHS Delegation 00170.1, Revision No. 01.2, paragraph (II)(92)(a).

■ 25. Add § 185.364 to subpart C to read as follows:

§ 185.364 Use of potentially hazardous items for commercial purposes.

On vessels described by 46 CFR 175.110(c), flammable items not otherwise covered by the regulations of this subchapter, such as rechargeable batteries, including lithium ion batteries utilized for commercial purposes, must be handled, stored, and operated in a way that mitigates the risk of hazardous conditions.

■ 26. Amend § 185.410 as follows:

■ a. Redesignate the introductory text as paragraph (a); and

■ b. Add paragraph (b).

The addition reads as follows:

§ 185.410 Watchmen.

* * * * *

(b) Vessels described by 46 CFR 175.110(d) must submit plans to the cognizant OCMI, in accordance with 46 CFR 176.700, for the installation and use of monitoring device to ensure the

wakefulness of the watchmen required in paragraph (a) of this section. Vessels with a keel laid date after March 28, 2022, must include plans for the monitoring device(s) within the plan submissions required in 46 CFR 177.202. The Coast Guard will work with the vessel operators to determine a reasonable implementation schedule once the plans are accepted. The monitoring device(s) must:

(1) Ensure the wakefulness of the crew in the event that the watchman required in paragraph (a) of this section is unresponsive;

(2) Remain operable during the nighttime watch; and

(3) Be arranged to ensure proper coverage of the passenger accommodation spaces, common areas, and spaces with potential fire hazards.

■ 27. Amend § 185.420 as follows:

■ a. Redesignate paragraphs (b) and (c) as paragraphs (c) and (d);

■ b. Add new paragraph (b); and

■ c. In newly redesignated paragraph (c):

■ i. Add the text ‘‘, monthly,’’ after the word ‘‘initial’’; and

■ ii. Remove the text ‘‘paragraph (a)’’ and add, in its place, the text ‘‘paragraphs (a) and (b)’’.

The addition reads as follows:

§ 185.420 Crew training.

* * * * *

(b) For a vessel described by 46 CFR 175.110(c), the training program in paragraph (a) of this section must address firefighting proficiency and must include, but need not be limited to—

(1) Training in the use and location of firefighting equipment and general firefighting knowledge, including:

(i) Location of firefighting appliances and emergency escape routes;

(ii) Types and sources of ignition;

(iii) Flammable materials, fire hazards and spread of fire;

(iv) The need for constant vigilance;

(v) Actions to be taken on board;

(vi) Fire and smoke detection and automatic systems on board; and

(vii) Classification of fire and applicable extinguishing agents.

(2) The drills required by § 185.524, including fire location and fire type; and

(3) Emergency egress training for each member of the crew, to occur for all members of the crew—

(i) At least monthly while such members are employed on board the vessels; and

(ii) Each time a crew member joins the crew of such vessel.

* * * * *

■ 28. Add § 185.507 to read as follows:

§ 185.507 Passenger egress drills.

(a) The master of a vessel described by 46 CFR 175.110(d) must conduct passenger emergency egress drills from the passengers’ assigned overnight accommodation spaces prior to beginning an excursion with new passengers.

(1) If the passengers are not assigned an overnight accommodation space, the master of a vessel described by 46 CFR 175.110(d) must conduct passenger emergency egress drills from an accommodation space prior to beginning an excursion with new passengers.

(2) For the purposes of this section, excursion includes anytime the vessel gets underway, or anytime passengers remain overnight on the vessel.

(b) [Reserved]

■ 29. Delayed indefinitely, amend § 185.507 by adding paragraph (b) to read as follows:

§ 185.507 Passenger egress drills.

* * * * *

(b) Passenger egress drills must be logged or otherwise documented for review by the Coast Guard upon request. The drill entry must include the following information:

(1) Date and time of the drill; and

(2) Number of drill participants.

■ 30. Add § 185.515 to read as follows:

§ 185.515 Passenger safety bill.

(a) [Reserved]

(b) Each passenger safety bill required by this section must list:

(1) The embarkation station and the number and location of the survival craft to which each passenger is assigned, if applicable;

(2) The fire and emergency signal and the abandon ship signal;

(3) Essential action that must be taken in an emergency; and

(4) If immersion suits are provided for passengers, the location of the suits and illustrated instructions on the method of donning the suits.

■ 31. Delayed indefinitely, amend § 185.515 by adding paragraph (a) to read as follows:

§ 185.515 Passenger safety bill.

(a) On vessels described by 46 CFR 175.110(d), a passenger safety bill must be posted by the master in each cabin or stateroom, and in passenger accommodation spaces.

* * * * *

Dated: December 15, 2021.

J.W. Mauger,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Prevention Policy.

[FR Doc. 2021–27549 Filed 12–23–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 195

[Docket No. PHMSA–2017–0152; Amdt. No. 195–104]

RIN 2137–AF31

Pipeline Safety: Unusually Sensitive Areas for the Great Lakes, Coastal Beaches, and Certain Coastal Waters

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Interim final rule.

SUMMARY: PHMSA is amending the pipeline safety regulations to explicitly state that certain coastal waters, the Great Lakes, and coastal beaches are classified as unusually sensitive areas for the purpose of compliance with the hazardous liquid integrity management regulations. This amendment implements mandates contained in the Protecting our Infrastructure of Pipelines and Enhancing Safety (PIPES) Act of 2016, as amended by the PIPES Act of 2020. A hazardous liquid pipeline that could affect these newly designated areas must be included in an operator’s integrity management program.

DATES: The effective date of the interim final rule is February 25, 2022. Submit comments by February 25, 2022.

ADDRESSES: You may submit comments, identified by Docket No. PHMSA–2017–0152, by any of the following methods:

• *E-Gov Web: http://www.regulations.gov.* This site allows the public to enter comments on any **Federal Register** notice issued by any agency. Follow the online instructions for submitting comments.

• *Mail:* Docket Management System: U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

• *Hand Delivery:* DOT Docket Management System: West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9:00 a.m. and 5:00 p.m. ET, Monday through Friday, except Federal holidays.

- *Fax:* 202–493–2251.
- *Instructions:* Identify the Docket No. PHMSA–2017–0152, at the beginning of your comments. If you submit your comments by mail, submit two copies. If you wish to receive confirmation that PHMSA received your comments, include a self-addressed stamped postcard. Internet users may submit comments at *http://www.regulations.gov.*
- *Note:* All comments received are posted without edits to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.
- *Privacy Act:* In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*
- *Confidential Business Information:* 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 (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments in response to this notice 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 notice, it is important that you clearly designate the submitted comments as CBI. Pursuant to 49 Code of Federal Regulations (CFR) 190.343, you may ask PHMSA to provide confidential treatment to information you give to the agency by taking the following steps: (1) Mark each page of the original document submission containing CBI as ''Confidential;'' (2) send PHMSA a copy of the original document with the CBI deleted along with the original, unaltered document; and (3) explain why the information you are submitting is CBI. Submissions containing CBI should be sent to Sayler Palabrica, 1200 New Jersey Avenue SE, DOT: PHMSA—PHP–30, Washington, DC 20590–0001. Any commentary PHMSA receives that is not specifically designated as CBI will be placed in the public docket.
- *Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* Follow the online instructions for accessing the dockets. Alternatively, you may review the documents in person at the street address listed above.

FOR FURTHER INFORMATION CONTACT: Sayler Palabrica by phone at 202–744–0825 or via email at *sayler.palabrica@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

PHMSA issues this interim final rule (IFR) to satisfy mandates within the PIPES Act of 2016 (Pub. L. 114–183) and the PIPES Act of 2020 (Pub. L. 116–260) to expand application of PHMSA's integrity management (IM) requirements to approximately 2,905 additional miles of hazardous liquid and carbon dioxide pipelines [1] located within or that could affect the Great Lakes, coastal beaches, or ''certain coastal waters.'' The IFR will provide enhanced protection from hazardous liquid pipeline accidents similar to the 2010 Marshall, MI and the 2015 Refugio Beach, CA oil spills, and ensure that events like the anchor strike that damaged Enbridge's Line 5 in the Straits of Mackinac are promptly identified and remediated before they result in environmental damage.

Hazardous liquid pipelines that could affect a high consequence area (HCA) are subject to additional safety requirements. Specifically, such pipelines must be included in an IM program. An HCA is defined in 49 CFR 195.450 as *a commercially navigable waterway,* a *high population area,* an *other populated area,* or an *unusually sensitive area* (USA) as defined in § 195.6. Section 195.6 identifies two types of USAs, ''USA drinking water resources'' and ''USA ecological resources.'' Every USA is, therefore, also an HCA. Under § 195.452, an operator of a hazardous liquid pipeline that is located in a USA, or in an area where a release could affect a USA, is required to comply with IM requirements. Section 19 of the PIPES Act of 2016 amended 49 U.S.C. 60109(b)(2) and directed PHMSA to revise the definition of a USA in § 195.6(b) to explicitly state that the Great Lakes, coastal beaches, and marine coastal waters are USA ecological resources. Congress further clarified this mandate in Section 120 of the PIPES Act of 2020 (division R of the Consolidated Appropriations Act of 2021, Pub. L. 116–260). With this clarification, the PIPES Act of 2020 introduced and defined the term ''certain coastal waters'' to replace the undefined term ''marine coastal waters.'' Congress defined ''certain coastal waters'' as the ''territorial sea of the United States; the Great Lakes and their connecting waters; and the marine and estuarine waters of the United States up to the head of tidal influence.'' Furthermore, Congress defined the term ''coastal beach'' as ''any land between the high- and low-water marks of certain coastal waters.'' This IFR incorporates these terms and the statutory definitions into § 195.6, as directed by Congress.

PHMSA maintains a map of HCAs, excluding proprietary or security sensitive information, in the National Pipeline Mapping System (NPMS) pursuant to 49 U.S.C. 60132(d). PHMSA intends to map ''certain coastal waters'' and ''coastal beaches'' as a single data layer within the NPMS. PHMSA will generate this map based on a combination of geographic information system (GIS) data from the National Oceanic and Atmospheric Administration (NOAA) Clean Water Act [2] dataset, U.S. Environmental Protection Agency (EPA) Estuary Data Mapper,[3] and the NOAA Sea Level Rise Viewer.[4] Each of these datasets are generated by expert scientific agencies of the Federal government and are available on the internet for public viewing. These datasets are further described in section VI of this IFR. PHMSA seeks comments on the use of these datasets to represent the location of the statutory definitions of ''certain coastal waters'' and ''coastal beaches'' in the NPMS.

While the primary effect of the IFR is expanding the hazardous liquid pipeline mileage subject to IM program requirements, defining new USAs also affects the requirements for certain pipelines in rural areas. Proximity to a USA also determines if an onshore rural gathering line is a regulated rural gathering line subject to safety requirements described in § 195.11(b). Additionally, a pipeline categorized as a

[1] Hereinafter, references to ''hazardous liquid'' pipelines will refer to both hazardous liquid and carbon dioxide pipelines for simplicity, as they are both governed by 49 CFR part 195.

[2] NOAA Office for Coastal Management, ''Clean Water Act Dataset'' (Nov. 9, 2016), *https://catalog.data.gov/dataset/clean-water-act (last accessed October 13, 2021).*

[3] EPA, ''High End Scientific Computing—Estuary Data Mapper Dataset'' (Dec. 7, 2020), *https://www.epa.gov/hesc/estuary-data-mapper-edm* (last accessed June 21, 2021).

[4] NOAA Office for Coastal Management, ''Sea Level Rise Viewer Dataset'' (July 2020), *https://catalog.data.gov/dataset/noaa-digital-coast-sea-level-rise-and-coastal-flooding-impacts-viewer* (last accessed October 13, 2021).

Category 3 rural low-stress pipeline could become a Category 1 or Category 2 pipeline if it is located within ½ mile of a USA.

PHMSA is not changing the definition of ''offshore'' in §§ 192.3 or 195.2 as a part of this IFR. Those sections define ''offshore'' to mean beyond the line of ordinary low water along that portion of the coast of the United States that is in direct contact with the open seas and beyond the line marking the seaward limit of inland waters. The new USAs defined in § 195.6 do not affect the definition of ''offshore'' in §§ 192.3 or 195.2. Even if data used to map the new USAs refer to ''offshore'' areas as defined or designated by a separate statute, such as the Submerged Lands Act (43 U.S.C. 1301 *et seq.*), the regulatory definition of ''offshore'' in §§ 192.3 and 195.2 is distinct from these other statutes and will remain unchanged. In other words, the definitions of ''coastal beach'' and ''certain coastal waters'' exist independently of the definition of ''offshore'' in §§ 192.3 or 195.2. A pipeline could be located within certain coastal waters and be either ''onshore'' or ''offshore'' under §§ 192.3 and 195.2. Accordingly, altering the definition of ''offshore'' is beyond the scope of this IFR.

II. Hazardous Liquid Integrity Management

The objective of the hazardous liquid IM requirements at § 195.452 is to reduce the risks of pipeline spills in areas where a release could have significant consequences. In a series of final rules published between 2000 and 2002, PHMSA's predecessor agency, the Research and Special Programs Administration, promulgated regulations that defined HCAs and required operators to develop and implement IM programs for each hazardous liquid pipeline that could affect an HCA in the event of a release. HCAs are defined in § 195.450 and represent areas where a release could have significant adverse consequences to human health and safety, the environment, and commercial navigation. The IM requirements that operators must implement to protect HCAs are specified in § 195.452.

IM requirements for hazardous liquid pipelines were implemented in four final rules. The first final rule was ''Pipeline Integrity Management in High Consequence Areas (Hazardous Liquid Operators with 500 or More Miles of Pipeline),'' [5] followed by ''Areas Unusually Sensitive to Environmental Damage,'' [6] and ''Pipeline Integrity Management in High Consequence Areas (Hazardous Liquid Operators with Less Than 500 Miles of Pipelines).'' [7] PHMSA made updates to these requirements in a 2019 final rule titled ''Safety of Hazardous Liquid Pipelines.'' [8] These rules established a regulatory framework focused on risk identification, assessment, and mitigation. PHMSA's IM regulations require operators of pipelines located in areas where a release could affect an HCA to take additional steps to address threats to the integrity of those pipelines by operating and maintaining those pipelines in accordance with an effective IM program. These measures require operators to devote additional analysis, assessment, and remediation resources to protect HCAs from pipeline releases that could adversely affect human health and safety, cause environmental damage, and disrupt commercial navigation.

A. High Consequence Areas

Section 195.450 of the existing hazardous liquid pipeline safety regulations defines an HCA as: (1) A *commercially navigable waterway,* which means a waterway where a substantial likelihood of commercial navigation exists; (2) a *high population area,* which means an urbanized area, as defined and delineated by the U.S. Census Bureau, that contains 50,000 or more people and has a population density of at least 1,000 people per square mile; (3) an *other populated area,* which means a place, as defined and delineated by the U.S. Census Bureau, that contains a concentrated population, such as an incorporated or unincorporated city, town, village, or other designated residential or commercial area; or (4) an *unusually sensitive area,* which is defined in § 195.6 to be a drinking water or ecological resource area that is unusually sensitive to environmental damage from a hazardous liquid pipeline release. Section 195.452(d)(2) requires operators to incorporate newly identified HCAs into their baseline assessment plans within one year from the date the area is identified, and complete a baseline assessment of any pipeline that could affect the newly identified HCA within 5 years from the date the area is so designated.

B. Unusually Sensitive Areas

Section 195.6 defines a USA as a drinking water or ecological resource area that is unusually sensitive to environmental damage from a hazardous liquid pipeline release. The regulatory definition of USA elaborates that a drinking water resource generally refers to a source of drinking water (*e.g.,* a surface water intake, a source water protection area for wells, or a recharge area for a karst aquifer) for a community water system, or a non-transient, non-community water system (*e.g.,* a school or factory) with no adequate alternative supply of drinking water. The definition of a USA ecological resource includes areas containing one or more critically imperiled species or ecological communities; a multi-species assemblage area; a migratory waterbird concentration area; and an area containing an imperiled, threatened, endangered species, depleted marine mammal species, or an imperiled ecological community containing species with a limited range.

C. Integrity Management Requirements

As described above, every USA is an HCA, and a hazardous liquid pipeline that could affect an HCA must be included in an operator's hazardous liquid IM program. Section 195.452(b) requires an operator to develop and follow a written IM program. Section 195.452(f) requires that a hazardous liquid pipeline IM program include each of the following elements:

- A process for identifying pipelines that could affect an HCA, including USAs (see §§ 195.6, 195.450, Appendix C to part 195, ''Guidance for Implementation of an Integrity Management Program'');
- A plan for scheduling and performing baseline assessments (§ 195.452(c));
- An analysis of pipeline safety risks that integrates all available information about pipeline integrity and potential consequences (§ 195.452(g));
- Criteria for performing remedial action in response to pipeline integrity issues identified during assessments or other analysis (§ 195.452(h));
- A continuous process for scheduling, performing, and interpreting integrity assessments and evaluations (§ 195.452(j));
- Identification of ''preventative and mitigative measures'' to protect the pipeline from identified integrity threats (§ 195.452(i));
- Procedures for evaluating the effectiveness of the IM program (§ 195.452(k)); and
- A process to ensure integrity assessment results and information analysis is performed by qualified personnel (§ 195.452(f)(8)).

[5] 65 FR 75377 (Dec. 1, 2000).

[6] 64 FR 9532 (Feb. 8, 2001).

[7] 67 FR 2136 (Jan. 16, 2002).

[8] 84 FR 52260 (Oct. 1, 2019).

When an operator determines that a pipeline segment could affect an HCA, it must integrate information about that segment, including information about potential consequences, into its risk analysis and add the segment to the baseline assessment plan. The minimum data attributes operators are required to consider are listed in § 195.452(g)(1). This includes information about the pipeline itself; excavation damage threats; information about the potential impacts of a release on an HCA; and data from integrity assessments, cathodic protection surveys, patrols, and other maintenance and surveillance tasks. This analysis is used to prioritize and schedule integrity assessments and identify preventative and mitigative measures.

If a pipeline segment could affect a newly identified USA as a result of this IFR, the operator must include that segment in their IM program and periodically assess the integrity of that segment. Section 195.452(d)(2) requires an operator to add pipelines that cross or could affect new HCAs into their baseline assessment plan within 1 year of obtaining that new HCA information and complete the baseline assessment within 5 years of that date. Section 195.452(c)(1)(i) requires that the baseline assessment be done with an in-line inspection tool unless construction or operational factors make an in-line inspection impracticable. The operator must select an in-line inspection tool, or combination of tools, capable of detecting, at a minimum, corrosion and dents. If cracking is identified as a probable integrity threat, then the operator must select a tool or combination of tools capable of detecting cracks. If an in-line inspection is impracticable, an operator may perform a baseline assessment using a pressure test, external corrosion direct assessment, or other technology with advance notification to PHMSA.

After the baseline assessment, a segment that could affect an HCA must be reassessed regularly. The assessment schedule for both the baseline assessment and reassessments must be established by considering all risk factors, including, at a minimum, each of the factors listed in § 195.452(e). Section 195.452(j)(3) requires operators to continually assess the pipeline's integrity at no greater than 5-year intervals, not to exceed 68 months, except as provided in § 195.452(j)(4). If the operator detects a defect during an assessment, the operator must remediate it pursuant to the requirements in § 195.452(h) and the operator's procedure. That paragraph requires an operator to establish repair criteria that meet minimum standards for remediation methods and repair of various repair conditions.

In addition to assessment and repair requirements, operators must use a risk analysis to identify preventative and mitigative measures necessary to avert negative impacts in HCAs. Examples of preventative and mitigative measures identified in § 195.452(i) include adopting damage prevention best practices, improving cathodic protection monitoring, shortening inspection intervals, installing emergency flow restricting devices,[9] installing leak detection equipment, or providing enhanced response training to operator personnel and emergency responders. Operators must implement preventative and mitigative measures based on an analysis of the likelihood of a pipeline release and the potential consequences of the release. The minimum elements of this risk analysis are described in § 195.452(i)(2). Pipelines that could affect an HCA must have a means to detect leaks on the pipeline system(s) pursuant to § 195.452(i)(3), though §§ 195.134 and 195.444 require leak detection systems on hazardous liquid pipeline systems outside of HCAs as well.

III. National Pipeline Mapping System

A. NPMS Introduction

PHMSA maintains a map of HCAs in the NPMS pursuant to 49 U.S.C. 60132(d). The NPMS includes GIS resources that allow users to view pipeline maps and pipeline operations information, depending on the profile of the user. The NPMS contains locations and information about gas transmission and hazardous liquid pipelines and liquefied natural gas (LNG) plants under PHMSA jurisdiction. The NPMS also contains hazardous liquid pipeline HCA data [10] and voluntarily submitted breakout tank [11] data. NPMS data for hazardous liquid pipeline facilities include geospatial data, attribute data for pipeline segments, metadata, and operator contact information. Operators are required to submit NPMS data annually or review their current data in the NPMS to confirm it is still accurate pursuant to § 195.61. PHMSA processes operator data submissions year-round and the online mapping applications and resources are updated approximately every other month. These data and submission requirements are described in further detail in § 195.61 and the Operator Standards Manual, available on the NPMS web page.[12]

The NPMS contains information from over 1,500 operators totaling over 225,000 miles of hazardous liquid pipelines and over 310,000 miles of gas transmission pipelines. Operators also voluntarily provided information on the location of 3,476 breakout tanks out of 8,412 reported in annual reports for the 2019 reporting year. PHMSA and others use NPMS data for a wide variety of purposes, including emergency response, inspection planning, risk assessment, regulatory support, spatial analysis, map production, public awareness, and education.

B. NPMS Access to Geospatial Data

The NPMS website is structured into three pages by user-type to facilitate access to available information and resources. The pages include: (1) The Government Official Portal, intended for government officials at the local, State, or Federal level, including emergency responders and tribal governments; (2) the Operator Portal, intended for employees of pipeline operators who contribute data to the NPMS, including operators of gas transmission or hazardous liquid pipelines, breakout tanks, and LNG plants under PHMSA jurisdiction; [13] and (3) the General Public Portal, available for members of the public. The General Public Portal includes information about gas transmission and hazardous liquid pipelines, an operator directory, and the NPMS Public Map Viewer for exploring or printing NPMS maps on a per-county basis. The General Public Portal also has maps of HCAs. This includes the location of high-population areas derived from U.S. Census Bureau data and commercially navigable waterways from the U.S. Army Corps of Engineers' National Waterway Network. As an initial step to implement Section 19 of the PIPES Act of 2016, PHMSA, in 2019, incorporated GIS data for the Great Lakes USA ecological resource to the NPMS based on the definition of the Great Lakes from 33 U.S.C. 1268 and

[9] A check valve or a remote control valve as defined in § 195.450.

[10] While HCAs for hazardous liquid pipelines are defined areas under § 195.450, HCAs for gas pipelines are identified under § 192.903 based on the location, diameter, and maximum allowable operating pressure of the pipeline and the pipeline's proximity to nearby structures. *See also* 49 U.S.C. 60109(b).

[11] A breakout tank is a storage tank in a hazardous liquid pipeline system used as part of the transportation of hazardous liquids by pipeline. *See* § 195.2.

[12] PHMSA, ''National Pipeline Mapping System Standards for Pipeline, Liquefied Natural Gas and Breakout Tank Farm Operator Submissions'' (Oct. 2017). *https://www.npms.phmsa.dot.gov/Documents/Operator_Standards.pdf.* (last accessed June 21, 2021).

[13] Operators can also use the Operator Portal to access information regarding NPMS data submission requirements, procedures, and HCA GIS data layers to support IM program planning.

geospatial information from NOAA's U.S. State Submerged Lands dataset.[14] NOAA updates this dataset as needed to ensure accuracy in depicting Great Lakes shorelines and last updated the dataset in 2016.

In addition to the three user-type pages discussed above, PHMSA has also developed the Pipeline Information Management Mapping Application (PIMMA). PIMMA is a password-protected, web-based mapping application limited to government officials and pipeline operators. Each government user only has access to the maps of pipelines in their area of jurisdiction, and each operator user only has access to maps of the pipelines they operate. Government officials or operators can apply for PIMMA access or log in to PIMMA from the NPMS homepage. Information on how to use and access PIMMA is available within the Government Official and Operator Portals.

Government officials and operators can request access to pipeline facility GIS data from the NPMS for use in their own GIS. This option allows government officials and operators to produce maps and conduct analyses. Government officials and operators may also apply for access to the NPMS pipeline facility GIS data in their area of jurisdiction or for the pipeline facilities they operate. Hazardous liquid operators may only access USA GIS data for the States in which they operate or are constructing hazardous liquid pipelines. Except for HCA and USA GIS data available on the General Public Portal (*i.e.,* populated areas, commercially navigable waterways, and the Great Lakes), all GIS data from the NPMS is considered for official use only and requires an application process that can include an official request letter from a pipeline company manager. Detailed instructions for access to GIS data from the NPMS are available on the NPMS website at *https://www.npms.phmsa.dot.gov/.* PHMSA conducts reviews of publicly available dataset updates every two years to maintain HCA data accuracy. PHMSA announces updates via emails to pipeline operators and on the NPMS website.

IV. Consequences of Hazardous Liquid Pipeline Spills in Coastal Areas and the Great Lakes

Any release of petroleum, petroleum products, or other hazardous liquids can adversely affect human health and safety, threaten wildlife and habitats, impede commercial navigation, or damage personal or commercial property. Spills into bodies of water present increased risk because the water and water currents act as conveyances to increase the spread of the spill. These factors greatly complicate response, recovery, and remediation efforts for spills affecting bodies of water and intertidal land along the shoreline. Major oil spills within the Great Lakes, shorelines, or coastal waters would have extreme, negative, and persistent impacts on shoreline ecology, benthic communities at the base of the ecosystem, fisheries, human health, and the economy of coastal communities. This IFR takes immediate action necessary to ensure that operators take appropriate steps to protect the Great Lakes, coastal communities, and marine waters from the impacts of hazardous liquid spills into these fragile environments. Although prediction of the precise number of avoided accidents realized by this rulemaking's extension of IM requirements to currently unregulated pipelines is challenging, the historical examples below underscore the magnitude of adverse environmental consequences for coastal beaches and coastal waters in the event of a significant pipeline accident.

The most recent significant pipeline accident that affected coastal beaches and coastal waters was a 2015 oil spill where a pipeline operated by Plains Pipeline, LP (Plains) failed due to external corrosion.[15] While this rupture occurred in an HCA and therefore was subject to PHMSA's IM requirements,[16] it highlights many of the probable impacts of oil pipeline spills into coastal areas. The rupture released 2,934 barrels (approximately 123,000 gallons) of heavy crude oil near Santa Barbara, California. Approximately 500 barrels (21,000 gallons) of crude oil reached the Pacific Ocean near Refugio State Beach. On March 13, 2020, the U.S. Department of Justice (DOJ) announced a settlement that required Plains pay over $60 million in penalties, clean-up costs, and natural resources assessment costs and damages.[17] This spill is estimated to have contaminated over 3,000 acres of shoreline, subtidal, and benthic habitats, and resulted in the injury or death to hundreds of birds and marine mammals.[18] In addition to the severe ecological impacts, the spill itself and cleanup activities significantly limited recreational and commercial use of the oil contaminated coastal beaches and surrounding areas.

Another accident demonstrating the significant adverse environmental consequences of pipeline spills into bodies of water was the rupture of Enbridge Line 6B, which occurred on July 26, 2010, near the town of Marshall, Michigan. While this spill occurred on a segment of pipe within an HCA [19] and along an inland, freshwater river, rather than along the coast, the adverse impacts resulting from this spill are similar to what could occur if a spill occurred in connecting waters of the Great Lakes estuaries, and other marine waters up to the head of tidal influence, which are specifically addressed in this rule. This accident occurred when a 30-inch pipeline ruptured, spilling approximately 20,000 barrels of diluted bitumen into the Kalamazoo River and surrounding wetlands. The release contaminated 40 miles of the Kalamazoo River, and cleanup efforts were complicated by the propensity for diluted bitumen and other heavy crude oils to sink. As a result of the spill, the impacted segment of the river remained closed for public, recreational use for nearly two years.[20] Environmental impacts continued in the years

[14] PHMSA, Press Release, ''PHMSA ID's Great Lakes as an Ecological Resource in NPMS'' (Oct. 21, 2019), *https://www.phmsa.dot.gov/news/phmsa-ids-great-lakes-ecological-resource-npms.*

[15] PHMSA, ''Failure Investigation Report: Plains Pipeline, LP, Line 901 Crude Oil Release, May 19, 2015—Santa Barbara County, California'' (May 2016), *https://www.phmsa.dot.gov/foia/plains-pipeline-lp-line-901-failure-investigation-report* (last accessed June 21, 2021).

[16] PHMSA and others brought a civil suit against Plains alleging, *inter alia,* that numerous violations of PHMSA's IM requirements contributed to the accident. *See United States of America, et al.* v. *Plains All America Pipeline,* L.P., Docket No. 2:20–cv–02415, Complaint at ¶¶ 130–158 (C.D. Cal. Mar. 13, 2020). Plains acceded to a consent decree resolving those violations. See *United States of America, et al.* v. *Plains All America Pipeline,* L.P., Docket No. 2:20–cv–02415, Consent Decree at ¶ 70 (C.D. Cal. Mar. 13, 2020).

[17] DOJ, ''U.S. Pipeline Company to Modify its National Operations to Implement Safeguards Resulting from Oil Spill'' (Mar. 13, 2020), *https://www.justice.gov/opa/pr/us-pipeline-company-modify-its-national-operations-implement-safeguards-resulting-oil-spill* (last accessed April 2, 2021).

[18] California Department of Fish and Wildlife et. al., ''Refugio Beach Oil Spill: Draft Damage Assessment and Restoration Plan/Environmental Assessment'' (April 22, 2020), *https://wildlife.ca.gov/OSPR/NRDA/Refugio* (last accessed June 21, 2021).

[19] Although this pipeline was subject to PHMSA's IM requirements, the operator's non-compliance with those requirements was a cause of the accident. While operator error is always possible, PHMSA believes that the inclusion of these requirements in this rulemaking will reduce the risk of future accidents. *See* PHMSA, CPF No. 3–2012–5013, In the Matter of Enbridge Energy Limited Partnership (Sept. 7, 2012), *https://primis.phmsa.dot.gov/comm/reports/enforce/documents/320125013/320125013_Final%20Order_09072012.pdf.*

[20] Klug, Fritz, ''Kalamazoo River reopens to the public, 2 years after Enbridge oil spill in Michigan,'' *Michigan Live* (Jan. 20, 2019), *https://www.mlive.com/news/kalamazoo/2012/06/see_what_sections_of_the_kalam.html.*

following the spill, including decreases in fish abundance and variety in downstream areas until at least 2013.[21] Enbridge agreed to pay over $1 billion in cleanup costs and $177 million in a settlement with DOJ, including $61 million in penalties.[22] Other events occurring on pipelines in or that could affect HCAs, such as a 2018 anchor strike that dented the submerged Enbridge Line 5 in the Straits of Mackinac,[23] and the October 2021 discovery of a large crude oil release from a pipeline near Huntington Beach, CA,[24] further highlight the damage that can be done by a pipeline spill into the Great Lakes or other coastal waters.

Non-pipeline spills in coastal areas have also resulted in widespread environmental damage and economic impacts. In 1969, an offshore oil production platform experienced a blowout off the coast of Santa Barbara, California. That accident contaminated 35 miles of California shoreline.[25] That event was the largest marine oil spill in U.S. history until the grounding of the crude oil tanker, Exxon Valdez, in Prince William Sound, Alaska in 1989,[26] and later the blowout of the Deepwater Horizon drilling rig in the Gulf of Mexico in 2010.[27] Each of these events led to widespread harm to marine and coastal ecosystems, and economic harm to coastal resources such as fisheries and recreational areas.

[21] U.S. Fish and Wildlife Service et al., ''Final Damage Assessment and Restoration Plan/Environmental Assessment for the July 25–26, 2010 Enbridge Line 6B Oil Discharges near Marshall, MI'' (Oct. 2015), *https://www.fws.gov/midwest/es/ec/nrda/MichiganEnbridge/#nrdar.*

[22] DOJ, ''United States, Enbridge Reach $177 Million Settlement After 2010 Oil Spills in Michigan and Illinois'' (July 20, 2016), *https://www.justice.gov/opa/pr/united-states-enbridge-reach-177-million-settlement-after-2010-oil-spills-michigan-and* (last accessed July 26, 2021).

[23] National Transportation Safety Board, MAB–19/12, ''Marine Accident Brief, Anchor Contact of Articulated Tug and Barge Clyde S VanEnkevort/Erie Trader with Underwater Cables and Pipelines'' (May 21, 2018), *https://www.ntsb.gov/investigations/AccidentReports/Pages/MAB1912.aspx.*

[24] PHMSA, CPF No. 5–2021–054–CAO, Corrective Action Order issued to Amplify Energy Corp. (Oct. 4, 2021), *https://www.phmsa.dot.gov/news/phmsa-corrective-action-order-amplify-energy-corporation-beta-offshore.*

[25] Mai-Duc, Christine, ''The 1969 Santa Barbara Oil Spill That Changed Oil and Gas Exploration Forever,'' *Los Angeles Times* (May 20, 2015), *https://www.latimes.com/local/lanow/la-me-ln-santa-barbara-oil-spill-1969-20150520-htmlstory.html.*

[26] EPA, ''Exxon Valdez Spill Profile—U.S. EPA Emergency Response,'' *https://www.epa.gov/emergency-response/exxon-valdez-spill-profile* (last accessed June 21, 2021).

[27] EPA, ''Deepwater Horizon—BP Gulf of Mexico Oil Spill—U.S. EPA Enforcement,'' *https://www.epa.gov/enforcement/deepwater-horizon-bp-gulf-mexico-oil-spill* (last accessed June 21, 2021).

V. Legislative and Administrative History

A. PIPES Act of 2016

With the passage of the PIPES Act of 2016, Congress amended 49 U.S.C. 60109(b) to add ''locations . . . that have been identified as part of the Great Lakes or have been identified as coastal beaches, [or] marine coastal waters'' to the list of ''areas where a pipeline rupture would likely cause permanent or long-term environmental damage.'' Section 19 of the PIPES Act of 2016 ordered that PHMSA ''revise section 195.6(b) of Title 49, Code of Federal Regulations, to explicitly state that the Great Lakes, coastal beaches, and marine coastal waters are USA ecological resources for purposes of determining whether a pipeline is located in a high consequence area.'' As described above, these areas will therefore be defined as HCAs, and operators of hazardous liquid pipelines that could affect such areas will be required to implement IM programs for those segments.

Based on the 2016 mandate, PHMSA searched for ''locations that have been identified as part of the Great Lakes or have been identified as coastal beaches, [or] marine coastal waters.'' During this search, described in section VI.B, PHMSA used the definition of the Great Lakes from 33 U.S.C. 1268 and geospatial information from NOAA's U.S. State Submerged Lands dataset and added the Great Lakes to the NPMS. PHMSA was unable to locate any existing U.S. statutory or regulatory provision(s) providing similarly helpful definitions of ''marine coastal waters'' or ''coastal beaches.'' Due to uncertainty regarding how to define ''locations . . . that have been identified as . . . coastal beaches [or] marine coastal waters'' as described in the PIPES Act of 2016, PHMSA held two public meetings, discussed below, and began drafting an advance notice of proposed rulemaking to seek public input on how to best define those terms in part 195 and provide GIS data representing the location of those areas in the NPMS.

B. Public Meetings

PHMSA held public meetings on November 17, 2017, and June 12, 2019, to discuss definitions for ''coastal beaches,'' ''marine coastal waters,'' [28] and ''the Great Lakes,'' and to identify GIS data sources to map such features in the NPMS. Both were in-person meetings in Washington, DC with options for remote participation. Materials presented during these meetings are available at the web page for each meeting.[29] The 2017 meeting included discussions on how PHMSA currently maps commercially navigable waterways in the Great Lakes. Representatives from PHMSA, NatureServe, NOAA, the Pipeline Safety Trust (PST), Phillips 66, Arcadis, and the Coastal and Marine Operators Pipeline Industry Initiative (CAMO) gave presentations. The meeting included discussions of potential data sources for shoreline types, what should be classified as a ''coastal beach,'' and where to define the landward and seaward extent of ''marine coastal waters.''

The 2019 meeting focused primarily on nine questions that PHMSA provided to attendees prior to the meeting, which included proposed definitions for ''locations that have been identified as part of the Great Lakes, or have been identified as coastal beaches, [or] marine coastal waters.'' Also discussed was the creation of new USA ecological resource GIS data based on the proposed definitions. PHMSA developed the proposed definitions and other questions for the 2019 public meeting after reviewing comments from the 2017 public meeting, the data pilot project,[30] and PHMSA's internal research. Question 9A, presented to the public meeting participants, included a discussion on whether PHMSA should use the GIS data depicting the extent of the U.S. State Submerged Lands dataset to map the Great Lakes and Question 9B referenced the statutory definition of the Great Lakes found in 33 U.S.C. 1268. PHMSA ultimately determined that the U.S. State Submerged Lands GIS data was the best mapping source to match the existing Great Lakes definition and added these data to the NPMS. This change is described in section VI.B. PHMSA, American Petroleum Institute (including Plains All American Pipeline, L.P. and Freeman GIS, Inc.), PST, and the Louisiana Department of Natural Resources each gave presentations during the 2019 meeting.

[28] As described in greater depth below, the PIPES Act of 2020 replaced the term ''marine coastal waters'' with ''certain coastal waters.''

[29] Materials from the November 2017 meeting can be found at *https://primis.phmsa.dot.gov/meetings/MtgHome.mtg?mtg=129;* materials from the June 2019 Meeting can be found at *https://primis.phmsa.dot.gov/meetings/MtgHome.mtg?mtg=142.* Those meeting materials are also available in the docket for this rulemaking at *https://www.regulations.gov/docket?D=PHMSA-2017-0094.*

[30] After the 2017 public meeting, PHMSA conducted a data pilot project to identify possible GIS data representing the definitions from the PIPES Act of 2016. The output of these data analyses are the suggested GIS data options and sample maps presented at the 2019 public meeting. These are available on the meeting page.

PHMSA requested that attendees post their questions and concerns to the docket for the meeting. Following the meeting, PHMSA worked to develop regulatory definitions and data sets addressing the challenges identified during the meeting and in public comments.

C. PIPES Act of 2020

The PIPES Act of 2020 eliminated the uncertainty regarding the undefined terms ''coastal beach'' and ''marine coastal waters,'' as they appeared in the PIPES Act of 2016. Section 120 of the PIPES Act of 2020 amended Section 19 of the PIPES Act of 2016. Congress eliminated the term ''marine coastal waters'' and replaced it with ''certain coastal waters,'' which Congress defined as ''the territorial sea of the United States; the Great Lakes and their connecting waters; and the marine and estuarine waters of the United States up to the head of tidal influence.'' Furthermore, Congress defined ''coastal beach'' as ''any land between the high- and low-water marks of certain coastal waters.'' Congress directed PHMSA to incorporate those definitions within its regulations not later than 90 days after the enactment. This rule therefore incorporates the statutory definitions of ''certain coastal waters'' and ''coastal beach'' into § 195.6 verbatim. Nevertheless, PHMSA invites comments on its plan to implement this mandate in the NPMS, which is described in section VI.

VI. Summary of Amendments

A. Revisions to § 195.6

Pursuant to the plain language of Section 19 of the PIPES Act of the 2016, as amended by the PIPES Act of 2020, this IFR amends § 195.6 to explicitly state that the Great Lakes, coastal beaches, and certain coastal waters are USA ecological resources for the purposes of determining whether a pipeline is in an HCA, as defined in § 195.450. In the IFR, PHMSA has revised § 195.6(c) to include the terms ''coastal beach'' and ''certain coastal waters,'' employing the statutorily mandated definitions in the PIPES Act of 2020. The implementation of these definitions in the NPMS is described in sections VI.B and VI.C below. This change also influences whether certain onshore rural gathering lines are regulated under § 195.11. The requirements for certain onshore rural gathering lines within ¼ mile of a USA are described in section VI.D below.

''Certain coastal waters'' are defined in this rule as ''the territorial sea of the United States; the Great Lakes and their connecting waters; and the marine and estuarine waters of the United States up to the head of tidal influence.'' This language mirrors the definition provided in the PIPES Act of 2020. Pursuant to Presidential Proclamation 5928,[31] the territorial sea of the United States extends 12 nautical miles (approximately 13.8 miles) from the baseline of the United States.[32] Generally, the baseline is drawn at the line of Mean Lower Low Water, or the lowest of the two low tides per day averaged over an 18.6-year period, as determined by NOAA; however, a straight baseline is allowed in some circumstances.[33] In other words, the territorial sea portion of ''certain coastal waters'' extends from approximately the line of low tide to 12 nautical miles out to sea. The ''marine and estuarine waters of the United States up to the head of tidal influence'' refers to waters inland of the landward limit of the territorial sea up to the upstream limit of water affected by the tide.[34]

As discussed in section VI.B below, PHMSA was able to use the existing expert agency definition and data to identify the Great Lakes; PHMSA had already included the Great Lakes and connecting waters in the NPMS consistent with the existing statutory definition in 33 U.S.C. 1268. The Great Lakes and connecting waters include Lake Ontario, Lake Erie, Lake Huron (including Lake St. Clair), Lake Michigan, and Lake Superior, and the connecting channels (Saint Mary's River, Saint Clair River, Detroit River, Niagara River, and the Saint Lawrence River to the Canadian border). This GIS dataset similarly relies on NOAA shoreline data.

The term ''coastal beach'' is defined in the PIPES Act of 2020, and therefore, defined in this IFR as ''any land between the high- and low-water marks of certain coastal waters.'' While earlier public meetings considered how the term ''coastal beach'' might apply to different shoreline types, the term ''coastal beach'' as defined the PIPES Act of 2020 directed that ''coastal beach'' covers ''any land between the high- and low-water marks of certain coastal waters,'' meaning intertidal land adjoining coastal waters, regardless of geomorphologic characteristics. Further, the Great Lakes are considered non-tidal.[35]

B. The Great Lakes in the NPMS

On October 21, 2019, PHMSA added the Great Lakes as a USA in the NPMS based on the mandate in Section 19 of the PIPES Act of 2016.[36] As described above, PHMSA defined the Great Lakes using an existing statutory definition at 33 U.S.C. 1268. PHMSA then selected corresponding geospatial information from the NOAA U.S. State Submerged Lands dataset to map the Great Lakes in the NPMS as a USA ecological resource based on that definition. PHMSA has not received any feedback on this approach and has determined that this information is consistent with the updated mandates in the PIPES Act of 2020, as it includes each of the Great Lakes and the connecting waters. Nevertheless, PHMSA seeks comments on the selection of this definition of the Great Lakes and the mapping data used to represent the location of the Great Lakes.

C. Certain Coastal Waters and Coastal Beaches in the NPMS

As described above, PHMSA maintains GIS data of HCAs, including USAs, as part of the NPMS. PHMSA intends to map both ''certain coastal waters'' and ''coastal beaches'' as USAs in a single GIS dataset available from the NPMS using a composite of the data sets described in this section. The datasets prepared by the EPA and NOAA described here are developed through the collection of tidal and environmental data. These data, collected over years, establishes the location of ''coastal beaches'' and

[31] 54 FR 777 (Jan. 9, 1989).

[32] Although Presidential Proclamation 5928 contemplated that an earlier, 3 nautical mile boundary of the ''territorial sea of the United States'' would continue to apply in some regulatory regimes (*e.g.,* in connection with the Clean Water Act (CWA, 33 U.S.C. 1251 *et seq.*)), PHMSA understands a 12 nautical mile boundary to be appropriate here. As noted elsewhere in this IFR, NOAA—in its literature and its GIS datasets—describes the ''territorial sea'' as being defined by a 12 nautical mile seaward boundary. Further, NPMS data yields that PHMSA's oversight of hazardous liquid pipelines under the pipeline safety regulations currently extends to a number of offshore pipelines located between the 3 nautical mile and the 12 nautical mile lines. Therefore, defining the seaward extent of the ''territorial sea of the United States'' by reference to a more limiting, 3 nautical mile boundary would not protect the environmental resources Congress sought to protect when incorporating that statutory language within the PIPES Act of 2020.

[33] Westington and Slagel, NOAA, ''U.S. Maritime Zones and the Determination of the National Baseline'' (2007), *https://www.gc.noaa.gov/pdfs/Westington_Slagel_2007.pdf.*

[34] NOAA, ''Definition for 'Head of Tide''' in ''NOAA Tides and Currents Glossary'' *https://tidesandcurrents.noaa.gov/glossary.html (last accessed June 21, 2021).*

[35] NOAA, ''Do the Great Lakes Have Tides?'' *https://oceanservice.noaa.gov/facts/gltides.html* (last accessed June 21, 2021).

[36] PHMSA, Press Release, ''PHMSA ID's Great Lakes as an Ecological Resource in NPMS'' (Oct. 21, 2019), *https://www.phmsa.dot.gov/news/phmsa-ids-great-lakes-ecological-resource-npms.*

''certain coastal waters'' as those terms were defined by Congress.

''Coastal beaches,'' as defined in the PIPES Act of 2020, extend from the high water mark to the low water mark, and the territorial sea portion of certain coastal waters extend from approximately the low water mars to the seaward extent of the U.S. territorial sea. Thus, the areas occupied by ''certain coastal waters'' and ''coastal beaches'' are contiguous and may overlap. This means that ''coastal beaches'' and the ''territorial sea of the United States'' GIS data to be mapped in the NPMS will cover all areas from near the line of high water to the seaward limit of the territorial sea of the United States. This entire area must now be considered as an ecological USA—and by extension, an HCA—for compliance with the IM requirements.

To provide GIS data representing the location of ''certain coastal waters'' and ''coastal beaches,'' PHMSA intends to create a single GIS dataset using a combination of data available from EPA and NOAA. Specifically, PHMSA intends to use the EPA Clean Water Act data prepared by NOAA, the EPA Estuary Data Mapper, and the NOAA Sea Level Rise Mean Higher High Water Data to create a single ''coastal beach'' and ''certain coastal waters'' USA dataset in the NPMS. PHMSA believes that aggregating these datasets from expert scientific Federal agencies represents the best-available national data on the location of ''certain coastal waters'' (the territorial sea of the United States, marine and estuarine waters of the United States up to the head of tide, and the Great Lakes), and ''coastal beaches'' (land between the high and low water marks). Each of these parent datasets are prepared and published by the expert agencies within the Federal government and are available to the public for download and review. The use of publicly available data addresses concerns about the availability of proprietary and security-sensitive information that were raised by the Pipeline Safety Trust and others during public meetings. PHMSA invites comments on the use of these datasets to satisfy the requirements of the PIPES Act of 2020.

PHMSA will use a portion of the GIS data NOAA compiled for EPA in compliance with the Clean Water Act (CWA) to represent the territorial sea portion of its new GIS dataset. Like the definition in the PIPES Act of 2020, the CWA refers to the territorial sea of the United States and the Great Lakes. The NOAA CWA dataset represents GIS data for the Great Lakes and connecting waters, as well as waters from the mean high-water line to the 12 nautical mile line (*i.e.,* the seaward extent of the U.S. territorial sea per Presidential Proclamation No. 5928) and the 3 nautical mile line used for certain Federal laws existing on or before the issuance of Presidential Proclamation No. 5928, including the CWA. The landward boundary in the CWA dataset is defined by the NOAA Medium Resolution Shoreline Product [37] for the contiguous U.S., and other Federal data [38] for the shoreline in Alaska, Hawaii, and Puerto Rico. For the purposes of identifying the location of ''certain coastal waters,'' the seaward extent of the U.S. territorial sea is mapped at the 12 nautical mile line depicted in the NOAA CWA dataset in accordance with the meaning of that term in Presidential Proclamation No. 5928 and international law. The NOAA Medium Resolution Shoreline represents the line of mean high water.[39] These data are compiled from official NOAA nautical charts and represents the definitive map of U.S. maritime boundaries (such as the seaward extent of the U.S. territorial sea) under U.S. and international law.

While the U.S. territorial sea under Presidential Proclamation No. 5928, as mapped by NOAA, definitively represents the U.S. territorial sea and the Great Lakes, it does not identify the location of marine and estuarine waters of the United States up to the head of tidal influence. In order to accurately represent such waters, PHMSA intends to include data from the EPA Estuary Data Mapper in the NPMS map of certain coastal waters and coastal beaches. The Estuary Data Mapper includes GIS polygon data for approximately 2,000 named estuaries of the United States. For the purposes of this dataset, EPA defines an estuary as:

> A partially enclosed body of water along the coast where freshwater from rivers and streams meet and mix with salt water from the ocean. Estuaries and the lands surrounding them are places of transition from land to sea, and although influenced by the tides, they are protected from the full force of ocean waves, winds, and storms by such landforms as barrier islands or peninsulas.

This definition explicitly references tidal influences. PHMSA understands the Estuary Data Mapper data represents the most complete national inventory of estuarine waters. These data are designed to support environmental science and management efforts and the EPA National Estuary Program.[40] The Estuary Data Mapper is a relatively new GIS product tool, and it is not entirely complete in Alaska, Hawaii, and some areas of the Pacific Northwest. Nonetheless, during the course of the development of this document, EPA has reported ongoing progress in this area.

The term ''coastal beaches'' includes all land between the high and low-water marks. The Medium Resolution Shoreline used in the EPA map of the U.S. territorial sea represents a location between high and low-water marks. As stated earlier, the Medium Resolution Shoreline represents the mean high water of the shore. NOAA defines ''mean high water'' as ''the average of all high-water heights observed over the National Tidal Datum Epoch.'' [41] In contrast, NOAA defines the ''high-water mark'' as ''[a] line or mark left upon tide flats, beach, or along shore objects indicating the elevation of the intrusion of high water. The mark may be a line of oil or scum on along shore objects, or a more or less continuous deposit of fine shell or debris on the fore shore or berm.'' [42] Because this physical line changes with each tidal shift, NOAA measures and records the ''higher high water'' (HHW), which is the ''higher of the two high waters of a tidal day where the tide is semidiurnal (occurring twice daily).'' The average of the HHW values is the tidal datum (*i.e.,* a fixed starting point) known as the ''mean higher high water'' (MHHW).

As described above, the ''high-water mark'' changes daily because it is influenced by meteorological, climate, and surf conditions. PHMSA is not aware of any national data representative of the physical high-water mark, which is dynamic and changes day to day. In the absence of this information, PHMSA will use the MHHW GIS data product from NOAA's Sea Level Rise Viewer to approximate

[37] NOAA, ''NOAA Medium Resolution Shoreline'' (Apr. 7, 2000), *https://shoreline.noaa.gov/data/datasheets/medres.html#:~:text=Abstract%3A%20NOAA's%20medium%2Dresolution%20shoreline,set%20created%20for%20general%20use.&text=The%20data%20set%20was%20created,Ocean%20Resources%20Conservation%20and%20Assessment (last accessed June 21, 2021).*

[38] For more information on these datasets, see the ''Lineage'' section of the metadata for this dataset *https://www.fisheries.noaa.gov/inport/item/48856.*

[39] *See* NOAA, ''Definition of 'Mean High Water' in Tides and Currents Glossary'' *https://tidesandcurrents.noaa.gov/glossary.html (last accessed June 21, 2021).*

[40] EPA, ''Frequently Asked Questions about Estuary Data Mapper'' *https://www.epa.gov/hesc/frequent-questions-about-estuary-data-mapper-edm (last accessed June 21, 2021).*

[41] NOAA, ''Tidal Datums'' *https://tidesandcurrents.noaa.gov/datum_options.html (last accessed June 21, 2021).*

[42] NOAA, ''Definition of 'High Water Mark' in ''Glossary of the NOAA Shoreline website'' *https://shoreline.noaa.gov/glossary.html* (last accessed June 21, 2021).

the location of the dynamic high-water mark. The NOAA Sea Level Rise Viewer includes digital elevation models and the NOAA tidal datum of mean higher high water. In certain locations and in certain meteorological conditions, the MHHW could be lower than a high-water mark. Nonetheless, the MHHW is the most accurate dataset that PHMSA is aware of for identifying the high-water mark and marine and estuarine waters up to the head of tidal influence. PHMSA acknowledges that MHHW may not precisely align with the exact physical high-water mark (indicated by fine debris or scum line) at any given time. In any event, the IM requirements apply not only to segments of hazardous liquid pipelines that cross an HCA but also to any pipeline segments that ''could affect'' an HCA. In determining which segments ''could affect'' an area, operators need to consider the terrain around the pipeline and natural forces inherent in the area, including tidal forces, meteorological conditions, and flood zones, when determining which pipeline segments could affect an HCA (See section I.B. of appendix C to part 195).

D. Requirements for Pipelines That Could Affect HCAs

As described in section II, changes to the definition of the term ''USA'' affect the hazardous liquid pipelines subject to IM requirements. Operators of hazardous liquid pipelines that could affect the Great Lakes, ''certain coastal waters,'' and ''coastal beaches'' must include those segments in an IM program. Based on a geospatial analysis using data in the NPMS, PHMSA estimates that 2,905 additional miles of hazardous liquid pipelines, primarily in states adjoining the Gulf of Mexico, will be subject to liquid IM requirements due to this IFR. This estimate reflects segments located within ¼ mile of any of the newly defined USAs but are not located within ¼ mile of the location of existing HCAs described in existing §§ 195.6 and 195.450. Based on this analysis, PHMSA anticipates that most affected operators have an existing IM program and will be able to extend that plan to include the newly covered segments. This analysis is described in the RIA for this IFR.

In addition, operators of onshore hazardous liquid pipelines submerged more than 150 feet below the surface of water that could affect an HCA must comply with enhanced requirements for submerged pipelines in self-executing provisions described in § 120(d) of the PIPES Act of 2020, codified at 49 U.S.C. 60109(g). That section of the pipeline safety laws (49 U.S.C. 60101 *et seq.*) requires that operators perform annual in-line inspections, annual route surveys, and have (and follow) procedures for assessing the potential impacts from third-party damage from vessels and maritime equipment, including anchors and anchor chains.

The presence of a USA also effects which onshore gathering lines are subject to part 195 safety requirements as regulated rural gathering lines. Section 195.2 defines a rural area as being outside the limits of any incorporated or unincorporated city, town, village, or any other designated residential or commercial area such as a subdivision, a business or shopping center, or community development. Currently, an onshore rural gathering line is subject to safety requirements in § 195.11 if the pipeline has a nominal diameter from 6⅝ inches to 8⅝ inches, has a stress level greater than 20 percent of the specified minimum yield strength (or a pressure of 125 pounds per square inch gauge (psig) for non-steel pipe or if the stress level is not known), and is located within ¼-mile of a USA. Defining new USAs may result in additional pipelines being classified as regulated rural gathering lines. However, PHMSA expects that the effect of the IFR on the mileage of onshore regulated rural gathering lines will be limited since rural gathering lines are not generally located along the coasts near most of the new USAs established by the IFR. Further, those rural gathering lines that are near the coasts may already be subject to part 195 requirements (pursuant to § 195.1) if they are either located in a non-rural area, cross commercially navigable waterways, or are located in the inlets of the Gulf of Mexico.[43] As discussed in the RIA, PHMSA estimates that 58.5 miles of currently unregulated rural gathering lines will become regulated, and that the resulting regulatory burden for those lines will be $63 thousand in the first year of analysis, and $15 thousand in years two through ten. PHMSA welcomes comment on its assumptions regarding the mileage and regulatory burden for currently unregulated gathering lines that become regulated as a result of the IFR, as well as corresponding safety benefits.

Rural gathering lines between 6⅝ inches and 8⅝ inches in diameter that become regulated rural gathering lines as a result of the IFR become subject to the requirements listed in § 195.11(b). An operator of a regulated rural gathering line must comply with reporting requirements in subpart B of part 195; establish a maximum operating pressure of the pipeline in accordance with § 195.406; install and maintain line markers in accordance with § 195.410; establish and carry out a public education program in accordance with § 195.440; establish and carry out a damage prevention program in accordance with § 195.442; comply with corrosion control requirements in subpart H; establish and carry out a program to identify internal corrosion in accordance with § 195.11(b)(10); and comply with operator qualification program requirements in accordance with subpart G to part 195 and § 195.505. A new or replaced regulated rural gathering line must also comply with the initial design, installation, construction inspection, and testing requirements in part 195, unless that pipeline is being converted to service under § 195.5. Pursuant to § 195.11(c), an operator most comply with § 195.11(b)(2)–(11) within 6 months from the date that a new USA has been identified, except for the requirements for corrosion control, which are subject to the compliance timelines in part 195, subpart H.

Finally, the part 195 requirements applicable to low-stress pipelines located in rural areas depend on the pipeline's proximity to a USA. Section 195.12 defines a low-stress rural pipeline as a line located in a rural area and having a maximum operating pressure corresponding to a stress level of 20 percent or less of the specified minimum yield strength (or if the stress level is unknown, or for non-steel pipelines, a pressure less than or equal to 125 psig). A rural low-stress line that is located within ½ mile of a USA (or alternatively, that could affect an HCA as determined in § 195.452(a)) is a Category 1 or Category 2 rural low-stress line that must comply with all of the safety requirements in part 195. Other rural low-stress pipelines not within ½ mile of a USA are Category 3 lines that must comply with all the requirements of part 195 except the IM program requirements in § 195.452. Pursuant to § 195.12(e), a Category 3 rural low-stress line or any other pipeline that becomes a Category 1 or Category 2 rural low-stress line must comply with the IM program requirements within 12 months following the date the USA is identified (*i.e.,* the effective date of this IFR). IM program requirements are described in detail above.

Because the IFR expands the scope of USAs, some Category 3 rural low-stress lines may become Categories 1 or 2 rural low stress lines and, therefore, would be

[43] PHMSA also notes that gathering lines larger than 8⅝ inches are already subject to part 195 safety requirements.

subject to IM program requirements at § 195.452(a). However, similar to the discussion of onshore regulated rural gathering above and as explained in the RIA, PHMSA understands relatively few rural low-stress pipelines will be affected by the IFR. Newly impacted rural low-stress lines located within ¼-mile of the new USAs are included in the RIA mileage estimate. However, PHMSA did not perform a separate analysis of rural-low stress lines located between ¼ mile and ½ mile of a newly designated USA. PHMSA expects the (current) Category 3 pipeline mileage which could be so affected to be minimal given that much of the rural low-stress lines near a coast would cross navigable waters and therefore would already be subject to IM program requirements under § 195.1. However, in 2020, operators reported only 3,100 miles of rural low-stress hazardous liquid lines total across all reported categories. Similar to the discussion of regulated rural gathering lines, much of the pipeline mileage near the new USAs (which are mostly along the coasts) is already subject to IM program requirements pursuant to the general applicability of part 195 to pipelines crossing navigable waters or that are located in the inlets of the Gulf of Mexico in § 195.1(a). Further, operators of rural low-stress liquid lines have the option to perform an HCA could-affect analysis under § 195.452(a) rather than use the ½-mile criteria.

VII. Effective Date and Comments

This IFR is effective without advance notice and public comment as the amendments to the CFR in the IFR are not subject to agency discretion. Section 19 of the PIPES Act of 2016, as amended by the PIPES Act of 2020 states that the Secretary ''shall revise section 195.6 [. . .] to explicitly state that the Great Lakes, coastal beaches and certain coastal waters are USA ecological resources.'' The PIPES Act of 2020 further specifies statutory definitions for each of these terms. Pursuant to the plain language of the mandates from the PIPES Act of 2016 and the PIPES Act of 2020, the IFR adopts each of these statutory definitions into § 195.6 verbatim. While PHMSA has no discretion regarding the amendments to § 195.6 mandated by the Act, this IFR invites comments on the national and publicly available GIS datasets to represent these new Ecological USA definitions in the NPMS.

PHMSA will consider all relevant, substantive comments in this area. PHMSA encourages interested parties to submit comments that: (1) Identify the amendments being commented on and the appropriate section numbers; (2) provide justification for their support or opposition to the amendments, especially data on safety risks and cost burdens; and (3) provide specific alternatives if appropriate.

VIII. Good Cause Exception

The Administrative Procedure Act (APA, 5 U.S.C. 551 *et seq.*) permits an agency to issue a final rule without first publishing a proposed rule for public comment when it demonstrates ''good cause'' that notice and comment is ''impracticable, unnecessary, or contrary to the public interest.'' 5 U.S.C. 552 (b)(3)(B). This exception is narrow, and PHMSA is proceeding with an IFR only in light of the specific instructions from Congress in the PIPES Act of 2020 that render comment both unnecessary and impracticable.

Prior notice and comment are unnecessary for this rulemaking because Congress, in the PIPES Act of 2020, provided clear, defined terms and required PHMSA to update its regulations to incorporate those terms. Specifically, Congress clarified that ''certain coastal waters'' means the territorial sea of the United States, the Great Lakes, and marine and estuarine waters up to the head of tidal influence. Congress also clarified which areas must be designated as a ''coastal beach.'' These statutory definitions resolved uncertainties within language in the PIPES Act of 2016 to expand the hazardous liquid pipelines subject to IM requirements. Congress did not provide discretion for PHMSA to adopt the regulatory amendments in this IFR, requiring PHMSA to ''revise § 195.6(b) to explicitly state that the Great Lakes, coastal beaches, and certain coastal waters are USA ecological resources for purposes of determining whether a pipeline is in a high consequence area.''

Notice and comment are also unnecessary because the definitions of the terms that Congress required PHMSA to include in its regulations are also further specifically defined by other expert Federal agencies, as described in the paragraphs that follow.

''The territorial sea of the United States'' has a long-established meaning based on Presidential Proclamation 5928, international law, and NOAA data sets. Each of these authorities define and designate the ''territorial sea of the United States,'' as extending 12 nautical miles (approximately 13.8 miles) from the ''baseline.'' NOAA is responsible for delineating the ''baseline,'' based on its tidal datum Mean Lower Low Water, or the lowest of the two low tides per day averaged over an 18.6-year period.

Next, NOAA has defined the boundaries of ''marine waters of the United States.'' While the term ''marine waters'' is not specifically defined in the U.S. Code, NOAA has defined ''marine waters'' as those waters subject to tidal influence. The seaward boundary of ''marine waters'' would be the extent of ''the territorial seas of the United States,'' as described above. The landward boundary of the ''marine waters'' is designated by NOAA's polygon GIS data identifying the MHHW values. These values are the averages of daily HHW recordings from NOAA tide stations over a period of 18.6 years.

EPA defines the boundaries of ''estuarine waters of the United States.'' The Clean Water Act authorizes EPA to define and map estuarine resources pursuant to the National Estuary Program provided for in the Clean Water Act (33 U.S.C. 1330). As described above, EPA similarly defines estuaries as subject to tidal influence. The EPA has also made estuary polygon data available in EPA's Estuary Data Mapper (EDM) that maps approximately 2,000 named estuaries identified using EPA's Environmental Monitoring and Assessment Program's National Coastal Condition Assessment.

NOAA has also defined the terms used in Congress' definition for ''coastal beaches.'' The PIPES Act of 2020 defines the term ''coastal beach'' to mean any land between the high- and low-water marks of certain coastal waters. As discussed above, NOAA has defined and mapped the MHHW, which is an authoritative tidal datum for approximating a ''high water mark.'' In contrast, the low water mark need not be defined for the purposes of the PIPES Act of 2020 because everything seaward of the high water mark is included in either the ''territorial sea of the United States,'' or the ''marine and estuarine waters of the United States up to the head of tidal influence''—terms which, as explained above, have been defined and mapped by NOAA and EPA.

Given the above, PHMSA has determined that it lacks discretion to alter or consider alteration of the long-standing definitions or practical understandings of ''the territorial sea of the United States,'' ''marine waters of the United States,'' ''estuarine waters of the United States,'' and ''coastal beaches.'' Similarly, PHMSA lacks discretion to alter or consider redesignation of the GIS polygons as depicted in NOAA's Clean Water Act data, the EPA EDM, and the NOAA Sea Level Rise MHHW Data. Changes to these definitions and designations would be inaccurate, would cause

confusion, and would be an unnecessary waste of government resources. Therefore, a traditional notice and comment rulemaking is unnecessary.

The Congressionally-specified regulatory language, along with an aggressive Congressional deadline, also render traditional notice and comment impracticable. In light of the earlier challenges PHMSA faced in defining and mapping the undefined terms ''marine coastal waters'' and ''coastal beaches,'' Congress in the PIPES Act of 2020 intervened in a pending PHMSA rulemaking (under the same RIN as this rulemaking) to ensure PHMSA had the tools—clear, defined terms in place of the ambiguous language in the PIPES Act of 2016—to resolve the bases for PHMSA's protracted delay in responding to an earlier rulemaking mandate. Congress also demanded PHMSA ''complete'' those regulatory amendments within 90 days of enactment of the PIPES Act of 2020. Congress' expectations regarding the need for prompt PHMSA action to complete this rulemaking is understandable given the history of hazardous liquid pipeline accidents that have affected or threatened coastal waters and the Great Lakes and other sensitive ecosystems. The negative environmental and human health impacts of hazardous liquid releases such as the 2010 Marshall, MI and 2015 Plains accidents persist for years, even despite best clean-up efforts. The 2018 anchor strike on Enbridge Line 5 further underscored the urgency of updating PHMSA's regulatory framework to address those risks. More recently, members of Congress have also identified the October 2021 discovery of a large crude oil release from a pipeline near Huntington Beach, CA, as evidence of the need for prompt PHMSA action to complete this rulemaking.[44]

Further delay of this IFR's regulatory revisions to accommodate notice and comment procedures would, therefore, frustrate an aggressive Congressional timeline for prompt completion of the specific regulatory amendments that Congress understood as being necessary to align PHMSA's IM regulations with the grave public safety and environmental risks posed by hazardous liquid lines. For those reasons, traditional notice and comment procedures are impracticable.

[44] *See* Letter from Reps. Graves & Crawford to Acting PHMSA Administrator Brown (Oct. 14, 2021), *https://republicans-transportation.house.gov/news/documentsingle.aspx?DocumentID=405635.*

IX. Regulatory Analyses and Notices

Legal Authority for This Rulemaking

This IFR is published under the authority of the Federal Pipeline Safety Laws. Section 60102 authorizes the Secretary of Transportation to issue regulations governing the design, installation, inspection, emergency plans and procedures, testing, construction, extension, operation, replacement, and maintenance of pipeline facilities. The Secretary has delegated this authority to the PHMSA Administrator under 49 CFR 1.97. Further, Section 19 of the PIPES Act of 2016, as amended by the PIPES Act of 2020, requires the Secretary of Transportation to revise § 195.6 to explicitly state in § 195.6 that the Great Lakes, certain coastal waters, and coastal beaches are USAs for the purpose of determining whether a hazardous liquid pipeline is in or could affect an HCA.

Executive Order 12866 and DOT Policies and Procedures for Rulemaking

Executive Order 12866 (''Regulatory Planning and Review'')[45] requires that agencies ''should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.'' Agencies should consider quantifiable measures and qualitative measures of costs and benefits that are difficult to quantify. Further, Executive Order 12866 requires that ''agencies should select those [regulatory] approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.'' Similarly, DOT Order 2100.6A (''Rulemaking and Guidance Procedures'') requires that regulations issued by PHMSA and other DOT Operating Administrations should consider an assessment of the potential benefits, costs, and other important impacts of the proposed action and should quantify (to the extent practicable) the benefits, costs, and any significant distributional impacts, including any environmental impacts. The Federal pipeline safety laws at 49 U.S.C. 60102(b)(5) further authorize only those safety requirements whose benefits (including safety and environmental benefits) have been determined to justify their costs.

Executive Order 12866 and DOT Order 2100.6A require that PHMSA submit ''significant regulatory actions'' to the Office of Management and Budget (OMB) for review. This IFR has been determined to be significant under section 3(f) of Executive Order 12866 and was reviewed by OMB. It is also considered significant under DOT Order 2100.6A. The Office of Information and Regulatory Affairs (OIRA) has not, however, designated this rule as a ''major rule'' as defined by the Congressional Review Act (5 U.S.C. 801 *et seq.*).

PHMSA estimates that the IFR will result in unquantified public safety and environmental benefits associated with preventing and mitigating hazardous liquid pipeline accidents within or that could affect coastal beaches, coastal waters, or the Great Lakes. PHMSA estimates annualized costs of between $3.91 million per year (using a 3 percent discount rate) and $3.98 million per year (using a 7 percent discount rate) due to costs associating with establishing or updating IM programs and performing integrity assessments. The costs and benefits of the IFR are described in further detail in the RIA, which is available in the docket.

Executive Order 13132

PHMSA analyzed this IFR in accordance with Executive Order 13132 (''Federalism'').[46] Executive Order 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may 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.''

This IFR does not have a substantial direct effect on State and local governments, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. This rulemaking action does not impose substantial direct compliance costs on State and local governments.

While the IFR may operate to preempt some State requirements, it does not impose any regulation that has substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. The pipeline safety laws, specifically 49 U.S.C. 60104(c), prohibit State safety regulation of interstate pipeline facilities. Although the pipeline safety laws allow States to augment pipeline safety requirements

[45] 58 FR 51735 (Oct. 4, 1993).

[46] 64 FR 43255 (Aug. 10, 1999).

for intrastate pipeline facilities, States may not issue safety requirements less stringent than those required by Federal law. A State may also regulate an intrastate pipeline facility PHMSA does not regulate.

In this instance, the preemptive effect of the IFR is limited to the minimum level necessary to achieve the objectives of the Federal pipeline safety law under which the IFR is promulgated. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

Environmental Justice

DOT Order 5610.2C and Executive Orders 12898 (''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations''),[47] 13985 (''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government''),[48] 13990 (''Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis''),[49] and 14008 (''Tackling the Climate Crisis at Home and Abroad'') [50] require DOT Operating Administrations to achieve environmental justice as part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects, including interrelated social and economic effects, of their programs, policies, and activities on minority populations, low-income populations, and other disadvantaged communities.

PHMSA has evaluated this IFR under DOT Order 5610.2C and the Executive Orders listed above and has determined it will not cause disproportionately high nor adverse human health and environmental effects on minority populations, low-income populations, or other underserved and disadvantaged communities. The IFR is facially neutral and national in scope; it is neither directed toward a particular population, region, or community, nor is it expected to adversely impact any particular population, region, or community. Indeed, because PHMSA expects the rulemaking will reduce the safety and environmental risks associated with hazardous liquid pipelines generally, PHMSA understands the regulatory amendments introduced by this IFR will, in fact, reduce any disproportionate human health and environmental risks for minority populations, low-income populations, or other underserved and other disadvantaged communities in the vicinity of pipelines within the scope of the IFR's amendments.

Executive Order 13175

PHMSA analyzed this IFR in accordance with the principles and criteria in Executive Order 13175 (''Consultation and Coordination with Indian Tribal Governments'') [51] and DOT Order 5301.1 (''Department of Transportation Programs, Polices, and Procedures Affecting American Indians, Alaska Natives, and Tribes''). Executive Order 13175 requires agencies to assure meaningful and timely input from tribal government representatives in the development of rules that significantly or uniquely affect tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship and distribution of power between the Federal government and tribes.

PHMSA assessed the impact of the IFR and determined that it will not significantly or uniquely affect tribal communities or Indian tribal governments. The rulemaking's regulatory amendments are facially neutral and will have broad, national scope; PHMSA, therefore, does not expect this rulemaking to significantly or uniquely affect tribal communities, much less impose substantial compliance costs on Native American Tribal governments or mandate Tribal action. And insofar as PHMSA expects the rulemaking will improve safety and reduce environmental risks associated with hazardous liquid pipelines, PHMSA has concluded it will not entail disproportionately high adverse risks for Tribal communities. The funding and consultation requirements of Executive Order 13175 do not apply.

Regulatory Flexibility Act, Executive Order 13272

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires Federal agencies to conduct a Regulatory Flexibility Analysis (RFA) for any rule subject to notice-and-comment rulemaking under the APA unless the agency head certifies that the rule will not have a significant economic impact on a substantial number of small entities. This final rule was developed in accordance with Executive Order 13272 (''Proper Consideration of Small Entities in Agency Rulemaking'') [52] to promote compliance with the RFA and to ensure that the potential impacts of the rulemaking on small entities has been properly considered.

As discussed above, PHMSA has determined that there is ''good cause'' to forego prior notice and comment and amend the pipeline safety regulations through this IFR. The Regulatory Flexibility Act, therefore, does not require PHMSA to conduct an RFA. Nonetheless, PHMSA conducted a screening analysis of the impact of the IFR on small entities, which is included in a final RFA within the rulemaking docket. As explained at greater length in that RFA, PHMSA has analyzed NPMS data and determined that only a small share of hazardous liquid pipeline mileage nationwide will be affected by the IFR—and the operators of most of that mileage either (1) already have IM programs, or (2) are not small entities. Further, the compliance costs incurred by even the handful of small entities that would be affected will not be ''significant'' under the Regulatory Flexibility Act. For these reasons, PHMSA certifies that the IFR will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) establishes policies and procedures for controlling paperwork burdens imposed by Federal agencies on the public. Pursuant to 44 U.S.C. 3506(c)(2)(B) and 5 CFR 1320.8(d), PHMSA must provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. PHMSA expects this IFR to impact the information collections described below.

PHMSA will submit an information collection revision request to OMB for approval based on the requirements in this IFR. The following information is provided for each affected information collection: (1) Title of the information collection; (2) OMB control number; (3) current expiration date; (4) type of request; (5) abstract of the information collection activity; (6) description of affected public; (7) estimate of total annual reporting and recordkeeping burden; and (8) frequency of collection. The information collection burden for the following information collection is estimated to be revised as follows:

1. Title: Hazardous Liquid Pipeline Assessment Requirements.

OMB Control Number: 2137–0605.

Current Expiration Date: 4/30/23.

Abstract: This information collection covers documentation and notifications associated with hazardous liquid pipeline IM requirements. These requirements include documentation of

[47] 59 FR 7629 (Feb. 16, 1994).

[48] 86 FR 7009 (Jan. 20, 2021).

[49] 86 FR 7037 (Jan. 20, 2021).

[50] 86 FR 7619 (Feb. 1, 2021).

[51] 65 FR 67249 (Nov. 9, 2000).

[52] 67 FR 53461 (Aug. 16, 2002).

continual assessment and evaluation and preventative and mitigative measures. PHMSA estimates that the new USA definitions in the IFR will require 6 operators to create new IM programs, resulting in 46,640 hours of additional burden to prepare an IM program and integrate safety information in the first year and 1,860 hours of additional burden each subsequent year. This results in an average annual burden increase of 16,787 hours per year over 3 years. PHMSA estimates that the remaining 105 affected operators are already subject to IM requirements, and therefore already have an IM program and perform annual updates.

Affected Public: Hazardous Liquid Pipeline Operators.

Total Reporting and Recordkeeping Burden:

Total Annual Responses: 10,509.

Total Annual Burden Hours: 342,394 hours.

Frequency of Collection: Regular.

2. Title: Qualification of Pipeline Safety Training.

OMB Control Number: 2137–0600.

Current Expiration Date: 11/30/2024.

Abstract: This information collection covers requirements to make and maintain training and qualification records of pipeline operating personnel. For hazardous liquid pipeline operators, these requirements are described in subpart G of part 195. These records include identification of individuals qualified to perform covered tasks, the covered tasks they are qualified to perform, and the method and date they were qualified. These records must be maintained while the individual is performing qualified tasks, or 5 years after the individual is no longer performing covered tasks. PHMSA estimates that the new USA definitions in the IFR will require operators of rural gathering lines regulated under § 195.11 to keep records of qualification for 30 additional individuals. This results in an average annual burden increase of 5 responses and 1 hour per year over 3 years.

Affected Public: Hazardous Liquid Pipeline Operators.

Total Reporting and Recordkeeping Burden:

Total Annual Responses: 29,172.

Total Annual Burden Hours: 2,293 hours.

Frequency of Collection: Regular.

3. Title: Transportation of Hazardous Liquids by Pipeline: Recordkeeping and Accident Reporting.

OMB Control Number: 2137–0047.

Current Expiration Date: 3/31/2024.

Abstract: This information collection covers hazardous liquid pipeline accident report requirements in § 195.50 and general recordkeeping burden associated with complying with Federal hazardous liquid pipeline safety regulations in part 195. PHMSA estimates that the new USA definitions in the IFR will require 2 operators of rural gathering pipelines that become regulated under part 195.11 to establish recordkeeping programs to comply with part 195 requirements applicable to regulated rural gathering pipelines. This results in an average annual burden increase of 2 responses and 272 hours per year over 3 years. PHMSA estimates that 4 additional operators of affected rural gathering liens already have part 195 recordkeeping programs associated with regulated assets that they operate. The reporting burden associated with accident reports is unchanged.

Affected Public: Hazardous Liquid Pipeline Operators.

Total Reporting and Recordkeeping Burden:

Total Annual Responses: 743.

Total Annual Burden Hours: 45,919 hours.

Frequency of Collection: Regular and on occasion.

4. Title: Public Awareness Program.

OMB Control Number: 2137–0622.

Current Expiration Date: 11/30/2024.

Abstract: This information collection covers records and reports generated in order to demonstrate compliance with public awareness program requirements. Hazardous liquid pipeline operators must comply with the public awareness program requirements in § 195.440. Program documentation and program evaluation results must be retained and be made available to Federal and State pipeline safety regulatory agencies. PHMSA estimates that the new USA definitions in the IFR will require 2 operators of rural gathering pipelines that become regulated under part 195.11 to establish recordkeeping programs to comply with public awareness program requirements. PHMSA estimates an average annual burden increase of 4 responses and 92 hours per year over 3 years associated with annual program development and program evaluation and update requirements. PHMSA estimates that 4 additional operators of affected rural gathering lines already have public awareness recordkeeping programs associated with regulated assets that they operate.

Affected Public: Hazardous Liquid Pipeline Operators.

Total Reporting and Recordkeeping Burden:

Total Annual Responses: 45,004.

Total Annual Burden Hours: 517,592 hours.

Frequency of Collection: Regular.

Those desiring to comment on these information collections should send comments directly to the Office of Management and Budget, Office of Information and Regulatory Affairs. Comments should be submitted on or prior to February 25, 2022 via email at the following address: *oira_submissions@omb.eop.gov.*

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA, 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector. For any NPRM or final rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate of $100 million or more (in 1996 dollars) in any given year, the agency must prepare, amongst other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate. As explained further in the RIA, PHMSA has determined that the IFR does not impose enforceable duties on State, local, or Tribal governments or on the private sector of $100 million or more (in 1996 dollars) in any one year. A copy of the RIA is available for review in the docket of this rulemaking.

Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

National Environmental Policy Act

The National Environmental Policy Act (NEPA, 42 U.S.C. 4321 *et. seq.*) requires Federal agencies to prepare a detailed statement on major Federal actions significantly affecting the quality of the human environment. The Council on Environmental Quality implementing regulations (40 CFR parts 1500–1508) require Federal agencies to conduct an environmental review considering (1) the need for the action, (2) alternatives to the action, (3) probable environmental impacts of the action and alternatives, and (4) the agencies and persons consulted during the consideration process. DOT Order 5610.1C (''Procedures for Considering Environmental Impacts'') establishes departmental procedures for evaluation

of environmental impacts under NEPA and its implementing regulations.

PHMSA analyzed this IFR in accordance with NEPA, NEPA implementing regulations, and DOT Order 5610.1C. PHMSA has prepared an environmental assessment (EA) and determined this action will not significantly affect the quality of the human environment. To the extent that the IFR has impacts on the environment, these are primarily beneficial ecological impacts from reducing the likelihood and consequences of hazardous liquid spills in coastal areas and the Great Lakes. A copy of the EA for this action is available in the docket. PHMSA invites comment on the environmental impacts of this IFR.

Executive Order 13211

Executive Order 13211 (''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'') [53] requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' That Executive Order defines a ''significant energy action'' as any action by an agency (normally published in the **Federal Register**) that promulgates, or is expected to lead to the promulgation of, a final rule or regulation (including a notice of inquiry, ANPRM, and NPRM) that (1)(i) is a significant regulatory action under Executive Order 12866 or any successor order and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.

This IFR is a significant action under Executive Order 12866; however, it is expected to have an annual effect on the economy of less than $100 million. Further, this IFR is not likely to have a significant adverse effect on supply, distribution, or energy use, as further discussed in the RIA. Further, OIRA has not designated this IFR as a significant energy action.

Executive Order 13609 and International Trade Analysis

Executive Order 13609 (''Promoting International Regulatory Cooperation'') [54] requires agencies consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA participates in the establishment of international standards to protect the safety of the American public. PHMSA has assessed the effects of the IFR and determined that it will not cause unnecessary obstacles to foreign trade.

List of Subjects in 49 CFR Part 195

Pipeline safety, Pipelines, Oil pollution.

[53] 66 FR 28355 (May 22, 2001).

[54] 77 FR 26413 (May 4, 2012).

In consideration of the foregoing, PHMSA is amending 49 CFR part 195 as follows:

PART 195—TRANSPORTATION OF HAZARDOUS LIQUIDS BY PIPELINE

■ 1. The authority citation for part 195 continues to read as follows:

Authority: 30 U.S.C. 185(w)(3), 49 U.S.C. 5121, 60101 *et seq.,* and 49 CFR 1.97.

■ 2. Amend § 195.6 as follows:

■ a. In paragraph (b)(4), remove the word ''or'' at the end;

■ b. In paragraph (b)(5), remove the period at the end and add in its place ''; or'';

■ c. Add paragraphs (b)(6) and (7);

■ d. Revise paragraph (c) introductory text; and

■ e. In paragraph (c) add definitions for the terms ''certain coastal waters'' and ''coastal beach'' in alphabetical order.

The additions and revision read as follows:

§ 195.6 Unusually Sensitive Areas.

* * * * *

(b) * * *

(6) A coastal beach; or

(7) Certain coastal waters.

(c) Definitions used in this part—

* * * * *

Certain coastal waters means the territorial sea of the United States; the Great Lakes and their connecting waters; and the marine and estuarine waters of the United States up to the head of tidal influence.

* * * * *

Coastal beach means any land between the high- and low-water marks of certain coastal waters.

* * * * *

Issued in Washington, DC, on December 16, 2021, under authority delegated in 49 CFR 1.97.

Tristan H. Brown,

Deputy Administrator.

[FR Doc. 2021–27751 Filed 12–23–21; 8:45 am]

BILLING CODE 4910–60–P

Proposed Rules

Federal Register
Vol. 86, No. 245
Monday, December 27, 2021

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.

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1240

RIN 2590–AB16

Capital Planning and Stress Capital Buffer Determination

AGENCY: Federal Housing Finance Agency.

ACTION: Notice of proposed rulemaking: Request for comments.

SUMMARY: The Federal Housing Finance Agency (FHFA or the Agency) is proposing to require the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac, and with Fannie Mae, each an Enterprise) to submit annual capital plans to the Agency and provide prior notice for certain capital actions (the proposal or proposed rule). The Agency is also incorporating the determination of the stress capital buffer into the capital planning process. The requirements in this proposal are consistent with the regulatory framework for capital planning for large bank holding companies.

DATES: Comments must be received on or before February 25, 2022.

ADDRESSES: You may submit your comments on the proposed rule, identified by regulatory information number (RIN) 2590–AB16, by any one of the following methods:

- *Agency website: www.fhfa.gov/open-for-comment-or-input.*
- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. If you submit your comment to the Federal eRulemaking Portal, please also send it by email to FHFA at *RegComments@fhfa.gov* to ensure timely receipt by FHFA. Include the following information in the subject line of your submission: Comments/RIN 2590–AB16.
- *Hand Delivered/Courier:* The hand delivery address is: Clinton Jones, General Counsel, Attention: Comments/RIN 2590–AB16, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. Deliver the package at the Seventh Street entrance Guard Desk, First Floor, on business days between 9 a.m. and 5 p.m.
- *U.S. Mail, United Parcel Service, Federal Express, or Other Mail Service:* The mailing address for comments is: Clinton Jones, General Counsel, Attention: Comments/RIN 2590–AB16, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. Please note that all mail sent to FHFA via U.S. Mail is routed through a national irradiation facility, a process that may delay delivery by approximately two weeks. For any time-sensitive correspondence, please plan accordingly.

FOR FURTHER INFORMATION CONTACT: Andrew Varrieur, Acting Senior Associate Director, Office of Capital Policy, (202) 649–3141, *Andrew.Varrieur@fhfa.gov;* Ron Sugarman, Principal Policy Analyst, Office of Capital Policy, (202) 649–3208, *Ron.Sugarman@fhfa.gov;* or Mark Laponsky, Deputy General Counsel, Office of General Counsel, (202) 649–3054, *Mark.Laponsky@fhfa.gov.* These are not toll-free numbers. For TTY/TRS users with hearing and speech disabilities, dial 711 and ask to be connected to any of the contact numbers above.

SUPPLEMENTARY INFORMATION:

Comments

FHFA invites comments on all aspects of the proposed rule. Copies of all comments will be posted without change and will include any personal information you provide, such as your name, address, email address, and telephone number, on the FHFA website at *https://www.fhfa.gov.* In addition, copies of all comments received will be available for examination by the public through the electronic rulemaking docket for this proposed rule also located on the FHFA website.

Table of Contents

I. Background

FHFA is proposing to require the Enterprises to submit annual capital plans to the Agency and provide prior notice for certain capital actions. The Agency is also incorporating the determination of the stress capital buffer from the final Enterprise Regulatory Capital Framework (ERCF) into the capital planning process. The requirements in this proposal are consistent with the regulatory framework for capital planning for large bank holding companies.

During the years leading up to the 2007 financial crisis, many financial institutions made significant distributions of capital, in the form of stock repurchases and dividends, without due consideration of the effects that a prolonged economic downturn could have on their capital adequacy and ability to continue to operate and remain credit intermediaries during times of economic and financial stress. In 2011, the Board of Governors of the Federal Reserve System (Board) first proposed amendments to Regulation Y (12 CFR 225.8) to require large banks to submit annual capital plans and to provide notice before making certain capital distributions.[1]

FHFA's proposal builds upon the Agency's existing supervisory expectation that the Enterprises should have robust systems and processes in place that incorporate forward-looking projections of revenue and losses to monitor and maintain their internal

[1] Originally, as a part of the capital plan rule, the Board could object to a firm's capital plan based on a qualitative assessment. However, amendments in 2019 changed this requirement such that after the 2020 Comprehensive Capital Analysis and Review (CCAR), no firm would be subject to a potential qualitative objection if the firm successfully passed several qualitative evaluations. All firms subject to the Board's capital plan rule have successfully passed the required number of qualitative evaluations such that no firms are subject to the qualitative objection going forward. In 2020, the Board's rule was amended to incorporate the stress capital buffer into the capital planning process. The Board made further updates to the rule in 2021, primarily to tailor the requirements based on risk.

capital adequacy. In FHFA's opinion, the Enterprises generally should operate with capital positions well above the minimum regulatory capital ratios, with the amount of capital held commensurate with each Enterprise's risk profile. The Enterprises should have internal processes for assessing their capital adequacy that reflect a full understanding of their risks and ensure that they hold capital corresponding to those risks to maintain overall capital adequacy.

The board of directors and senior management of the Enterprises are ultimately responsible for overseeing an Enterprise's capital planning strategies and internal capital adequacy processes. The proposal does not diminish the responsibility of the Enterprise and its board of directors and senior management with respect to capital planning. Rather, the proposal is intended to: (i) Establish minimum supervisory standards for such strategies and processes for the Enterprises; (ii) describe how the boards of directors and senior management of the Enterprises should communicate the strategies and processes, including any material changes to FHFA; and (iii) provide FHFA with an opportunity to review the Enterprises' planned capital distributions.

The proposal is also consistent with FHFA's practice of requiring company-run stress tests from each Enterprise. In 2014, the Agency began requiring its regulated entities to conduct stress tests pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act). As amended by section 401 of the Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA), the Dodd-Frank Act requires certain financial companies with total consolidated assets of more than $250 billion, and which are regulated by a primary federal financial regulatory agency, to conduct periodic stress tests to determine whether the companies have sufficient capital to absorb losses and support operations during adverse economic conditions.

Dodd-Frank Act stress testing (DFAST) is a forward-looking exercise that assesses the impact on capital levels that would result from immediate financial shocks and nine quarters of adverse economic conditions. FHFA requires Fannie Mae and Freddie Mac to submit the results of stress tests based on two scenarios: A baseline scenario and a severely adverse scenario. The Agency aligned its DFAST scenario variables and assumptions with those used by the Board for its stress testing of banks. The Agency's dates for the capital plan submission and initial notice of the stress capital buffer lag the timeline imposed by the Board by 45 days. This is due to differences in the timing of the implementation of the annual DFAST process for banks versus the Enterprises. FHFA provides the Enterprises with DFAST instructions and guidance with a 30-day lag after the Board issues instructions to the banks. The Enterprises also report DFAST results to FHFA with a 30-day lag compared to the banks reporting results to the Board. Under the proposal, the Enterprises would need to submit their capital plans to FHFA by May 20, the same date that the DFAST results are due to the Agency. FHFA and the Enterprises release DFAST results to the public between August 1 and August 15. By August 15, the Agency would also provide the Enterprises with initial notices of their stress capital buffers. The final stress capital buffers will be provided to the Enterprises on August 31 and they will be effective on October 1. These last two dates align with the banking timeline.

The Federal Housing Enterprises Financial Safety and Soundness Act of 1992 establishes minimum leverage ratios for the Enterprises by statute and requires FHFA to establish risk-based capital levels for an Enterprise by regulation. FHFA may also set higher leverage requirements by regulation. FHFA did both in the ERCF, published in the **Federal Register** on December 17, 2020 (85 FR 82198, 12 CFR part 1240).[2] FHFA may address an Enterprise's failure to meet a capital threshold that is required by statute or regulation through enforcement mechanisms. For example, pursuant to FHFA's Prompt Corrective Action and general enforcement authority, it may require an Enterprise to develop and implement a capital restoration plan, restrict asset growth or activities, and take other appropriate actions to remediate the violation of law.[3] The Agency may also use the enforcement tools available under its authority to prescribe and enforce prudential management and operations standards (PMOS).[4] The Enterprises are currently in conservatorship, are subject to the restrictions of the Senior Preferred Stock Purchase Agreements between them and the U.S. Treasury, and do not hold capital anywhere near the levels specified in the ERCF. The capital plans will allow the Enterprises to identify the amount of capital they need to raise to close the gap with the ERCF, and to consider the timing of when to raise capital, and what types of capital to raise. The provisions on capital distributions of this proposed rule, like those of the ERCF, are unlikely to be of practical effect soon. This proposed rule, like the ERCF, is intended to provide a stable regulatory framework for the Enterprises for an extended period, including after they achieve adequate capitalization under the ERCF.

II. Capital Plans

A. Annual Capital Planning Requirement

The proposal would require an Enterprise to develop and maintain a capital plan. For purposes of the proposal, a capital plan is defined as a written presentation of the Enterprise's capital planning strategies and capital adequacy processes that includes a set of mandatory elements.

An Enterprise must submit its complete capital plan to FHFA by May 20 of each calendar year, or such later date as directed by the Agency. The Enterprise's board of directors or a designated committee thereof must at least annually, review the robustness of the Enterprise's process for assessing capital adequacy, ensure that any deficiencies in the Enterprise's process for assessing capital adequacy are appropriately remediated, and approve the Enterprise's capital plan before it is submitted to the Agency.

B. Mandatory Elements of a Capital Plan

A capital plan would be required to contain at least the following elements:

1. An assessment of the expected sources and uses of capital over the planning horizon that reflects the Enterprise's size, complexity, risk profile, and scope of operations, assuming both expected and stressful conditions.

2. Estimates of projected revenues, expenses, losses, reserves, and pro forma capital levels, including regulatory capital ratios, and any additional capital measures deemed relevant by the Enterprise, over the planning horizon under a range of scenarios, including the Enterprise's Internal baseline scenario and at least one Internal stress scenario, as well as any additional scenarios that FHFA may

[2] FHFA subsequently proposed amendments to refine the prescribed leverage buffer amount and capital treatment of credit risk transfers, 86 FR 53230 (Sept. 27, 2021), and proposed a rule to introduce additional public disclosure requirements, 86 FR 60589 (Nov. 3, 2021).

[3] *See* 12 U.S.C. ch. 46, subch. II (Prompt Corrective Action), & subch. III (general enforcement authority).

[4] *See* 12 U.S.C. 4513b. The ERCF is a prudential standard for purposes of that statutory section, 12 CFR 1240.1(e)(3).

provide the Enterprise after giving notice to the Enterprise.

3. A discussion of the results of any stress test required by law or regulation, and an explanation of how the capital plan takes these results into account.

4. A description of all planned capital actions over the planning horizon. Planned capital actions must be consistent with any effective capital distribution limitations established by FHFA by order or regulation. The Enterprise must also consider its regulatory capital buffers in planning capital actions.

5. A discussion of how the Enterprise will, under expected and stressful conditions, maintain capital commensurate with its risks, and maintain capital above the regulatory capital ratios.

6. A discussion of how the Enterprise will, under expected and stressful conditions, maintain sufficient capital to continue its operations by maintaining ready access to funding, meeting its obligations to creditors and other counterparties, and continuing to serve as a credit intermediary.

7. The Enterprise's capital policy (defined below).

8. A discussion of any expected changes to the Enterprise's business plan that are likely to have a material impact on the Enterprise's capital adequacy or liquidity.

These proposed mandatory elements of a capital plan are consistent with FHFA's existing supervisory practice with respect to the information that it expects the Enterprises to include in a capital plan for internal planning purposes.

For purposes of the proposal, a capital action would be defined as any issuance of a debt or equity capital instrument, any capital distribution, and any similar action that FHFA determines could impact an Enterprise's consolidated capital.

A capital distribution would be defined as a redemption or repurchase of any debt or equity capital instrument, a payment of common or preferred stock dividends, a payment that may be temporarily or permanently suspended by the issuer on any instrument that is eligible for inclusion in the numerator of any minimum regulatory capital ratio, and any similar transaction that FHFA determines to be in substance a distribution of capital.

Capital policy would be defined as the written principles and guidelines used for capital planning, issuance, usage and distributions, including internal capital goals, quantitative or qualitative guidelines for distributions, strategies for addressing shortfalls and internal governance.

Internal baseline scenario would be defined as a scenario that reflects the Enterprise's expectation of the economic and financial outlook. Internal stress scenario would be defined as a scenario designed by an Enterprise that stresses the specific vulnerabilities of the Enterprise's risk profile and operations. Both scenarios would also include expectations related to the Enterprise's capital adequacy and financial condition.

The planning horizon would be defined as at least nine consecutive quarters for the FHFA scenarios, consistent with DFAST, and at least five years for the Internal scenarios, consistent with the Enterprise's corporate forecasts. FHFA's proposal differs from the banking framework, which has a nine-quarter horizon for both the regulator's scenarios and bank's Internal scenarios. The proposal's longer-term horizon for the Internal scenarios would better allow FHFA to assess each Enterprise's plan to rebuild capital to come into compliance with the ERCF.

An Enterprise must include pro forma estimates of its minimum regulatory capital ratios in its capital plan. If FHFA were to adopt additional or different minimum regulatory capital ratios in the future, an Enterprise would be required to incorporate these minimum capital ratios into its capital plan as they come into effect and reflect them in its planning horizon.

In connection with its submission of a capital plan to FHFA, an Enterprise would be required to provide certain data to FHFA. To the greatest extent possible, the data templates, and any other data requests, would be designed to minimize the burden on the Enterprise and to avoid duplication. Upon the request of FHFA, an Enterprise must provide the Agency with information on its financial condition and capital, structure, amount and risk characteristics of on- and off-balance sheet exposures, risk management policies and procedures, liquidity profile, models used for stress scenario analysis, and any other relevant qualitative or quantitative information requested by the Agency to facilitate review of the Enterprise's capital plan.

C. FHFA Review of a Capital Plan

The proposal provides that FHFA would consider the following factors in reviewing an Enterprise's capital plan:

1. The comprehensiveness of the capital plan, including the extent to which the underlying analysis addresses potential risks from activities across the Enterprise and the Enterprise's capital policy;

2. The reasonableness of the capital plan, assumptions and analysis underlying the capital plan and robustness of its capital adequacy process;

3. Relevant supervisory information about the Enterprise and its subsidiaries;

4. The Enterprise's regulatory and financial reports, and supporting data to allow for an analysis of the Enterprise's loss, revenue and reserve projections;

5. The results of any stress tests conducted by the Enterprise or FHFA; and

6. Other information required by FHFA or related to the Enterprise's capital adequacy.

D. Resubmission of a Capital Plan

1. Under the proposal, an Enterprise would be required to update and resubmit its capital plan to FHFA within 30 days if the Enterprise determines there has been or will be a material change in the Enterprise's risk profile, financial condition, or corporate structure since the last submitted plan to FHFA, or if the Agency directs the Enterprise in writing to revise and resubmit its plan, as necessary to monitor risks to capital adequacy, for reasons including, but not limited to: The capital plan is incomplete or the capital plan, or the Enterprise's internal capital adequacy processes, contains material weaknesses;

2. There has been or will likely be a material change in the Enterprise's risk profile (including a material change in its business strategy or any risk exposure), financial condition, or corporate structure;

3. The Internal stress scenario(s) in the capital plan are not appropriate for the Enterprise's business model and portfolios, or changes in financial markets or the macro-economic outlook that could have a material impact on an Enterprise's risk profile and financial condition require the use of updated scenarios.

FHFA may extend the 30-day resubmission period for up to an additional 60 days, or such longer period as the Agency determines appropriate.

If a capital plan is resubmitted by an Enterprise, FHFA will provide notice within 75 days, unless extended, on whether it will recalculate the stress capital buffer. Unless otherwise determined by FHFA, the Agency will provide notice to the Enterprise of the new buffer within 90 days of its decision to recalculate the buffer.

III. Approval Requirements for Certain Capital Actions and Post Notice Requirement

An Enterprise must receive prior approval from FHFA before making a capital distribution (excluding any capital distribution arising from the issuance of a capital instrument eligible for inclusion in the numerator of a regulatory capital ratio) if the capital distribution would occur after an event requiring the resubmission of a capital plan.

In making a request for a capital distribution under this part of the proposal, the Enterprise must discuss any changes to the capital plan since it was last submitted to FHFA, provide the purpose of the transaction, and a description of the proposed capital distribution. The Agency may request additional information, which may include an assessment of the Enterprise's capital adequacy under a severely adverse scenario, a revised capital plan, and supporting data.

FHFA will act on requests for prior approval within 30 days of receiving all the required information. If the transaction is not approved, the Agency will notify the Enterprise of the reasons for its decision, and the Enterprise will have 15 days to submit a request for a hearing. If after considering the request FHFA decides to grant a hearing, it will be held within 30 days of FHFA's receipt of the request for a hearing. The Agency will give written notice to the Enterprise of its decision within 60 days of the conclusion of the hearing. FHFA may decide to extend the periods for the hearing and for rendering its decision.

An Enterprise must notify FHFA within 15 days of making a capital distribution if it was approved under a request for prior approval (when a plan needs to be resubmitted), or if the distribution will exceed the dollar amount of the Enterprise's final planned capital distributions, as measured on an aggregate basis beginning in the fourth quarter of the planning horizon through the quarter at issue.

IV. Stress Capital Buffer

A. Determination of the Stress Capital Buffer

The proposal incorporates the stress capital buffer from the ERCF into the capital planning process. The buffer is determined by FHFA, and the calculation is based on the results of a supervisory stress test, subject to a floor of 0.75 percent of the Enterprise's adjusted total assets as of the last day of the previous calendar quarter. However, until such time as the Agency develops its supervisory stress test, or in any year that FHFA does not determine the stress capital buffer, the buffer is equal to 0.75 percent of an Enterprise's adjusted total assets, as of the last day of the previous calendar quarter.

The proposal has changed the calculation method slightly by considering an Enterprise's planned common stock dividends for the fourth through seventh quarters of the planning horizon rather than the ERCF direction to use each of the nine quarters of the planning horizon. This change is consistent with the Board's recent amendments to the banking rule, which uses four quarters of planned common stock dividends.

FHFA will provide the Enterprise with notice of its stress capital buffer and explanation of the results of the supervisory stress test by August 15 of each year, unless otherwise determined by the Agency. Within two business days of receiving its stress capital buffer, an Enterprise must adjust its planned capital distributions for the fourth through seventh quarters of the planning horizon to be consistent with effective capital distribution limitations assuming the stress capital buffer provided by the Agency, in place of any stress capital buffer currently in effect.

An Enterprise may request reconsideration of its stress capital buffer by submitting a written request within 15 days of receipt of its buffer from FHFA. The Enterprise may also request an informal hearing. The hearing, if granted by the Agency, will take place within 30 days of FHFA's receipt of the request for a hearing. FHFA will provide its decision within 30 days of receiving the written reconsideration request or within 30 days of the conclusion of the hearing. The time period for the hearing and for providing the decision may be extended by the Agency.

If the Enterprise does not request reconsideration, FHFA will provide the Enterprise with its final stress capital buffer by August 31 and the buffer will be effective on October 1, unless otherwise determined by the Agency.

B. Conforming Amendments to the ERCF

Since the proposal incorporates the stress capital buffer into the capital planning process, it is necessary for FHFA to make conforming amendments to the ERCF. The stress capital buffer determination in the ERCF would be replaced with a reference to the determination of the buffer in the capital planning rule. The stress capital buffer would remain as a component of the capital conservation buffer in the ERCF.

FHFA solicits comments on all aspects of the proposal.

V. Regulatory Analyses

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires that a regulation that has a significant economic impact on a substantial number of small entities, small businesses, or small organizations must include an initial regulatory flexibility analysis describing the regulation's impact on small entities. FHFA need not undertake such an analysis if FHFA has certified that the regulation will not have a significant economic impact on a substantial number of small entities. FHFA has considered the impact of the proposed rule under the Regulatory Flexibility Act. FHFA certifies that the proposed rule, if adopted as a final rule, would not have a significant economic impact on a substantial number of small entities because the proposed rule is applicable only to the Enterprises, which are not small entities for purposes of the Regulatory Flexibility Act.

B. Paperwork Reduction Act

The Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*) requires that regulations involving the collection of information receive clearance from the Office of Management and Budget (OMB). The proposed rule contains no such collection of information requiring OMB approval under the PRA. Therefore, no information has been submitted to OMB for review.

List of Subjects in 12 CFR Part 1240

Capital, Credit, Enterprise, Investments, Reporting and recordkeeping requirements.

Authority and Issuance

Accordingly, for the reasons stated in the preamble, under the authority of 12 U.S.C. 4511, 4513, 4513b, 4514, 4515–17, 4526, 4611–12, 4631–36, FHFA proposes to amend part 1240 of title 12 of the Code of Federal Regulations as follows:

Chapter XII—Federal Housing Finance Agency

Subchapter C—Enterprises

PART 1240—CAPITAL ADEQUACY OF ENTERPRISES

■ 1. The authority citation for part 1240 is revised to read as follows:

Authority: 12 U.S.C. 4511, 4513, 4513b, 4514, 4515, 4517, 4526, 4611–12, 4631–36.

■ 2. Amend § 1240.11 by revising paragraph (a)(7) to read as follows:

§ 1240.11 Capital conservation buffer and leverage buffer.

(a) * * *

(7) *Stress capital buffer.* (i) The stress capital buffer for an Enterprise is the stress capital buffer determined under § 1240.500 except as provided in paragraph (a)(7)(ii) of this section.

(ii) If an Enterprise has not yet received a stress capital buffer requirement per paragraph (a)(7)(i) of this section, its stress capital buffer for purposes of this part is 0.75 percent of the Enterprise's adjusted total assets, as of the last day of the previous calendar quarter.

* * * * *

■ 3. Add subpart H to read as follows:

Subpart H—Capital Planning and Stress Capital Buffer Determination

§ 1240.500 Capital planning and stress capital buffer determination.

(a) *Purpose.* This section establishes capital planning and prior notice and approval requirements for capital distributions by the Enterprises. This section also establishes FHFA's process for determining the stress capital buffer applicable to the Enterprises.

(b) *Scope and reservation of authority*—(1) *Applicability.* This section applies to the Enterprises.

(2) *Reservation of authority.* Nothing in this section shall limit the authority of FHFA to issue or enforce a capital directive or take any other supervisory or enforcement action, including an action to address unsafe or unsound practices or conditions or violations of law.

(c) *Definitions.* For purposes of this section, the following definitions apply:

Adjusted total assets has the same meaning as under subpart A of this part.

Advanced approaches means the risk-weighted assets calculation methodologies as set forth in subpart E of this part.

Capital action means any issuance of a debt or equity capital instrument, any capital distribution, and any similar action that FHFA determines could impact an Enterprise's consolidated capital.

Capital distribution means a redemption or repurchase of any debt or equity capital instrument, a payment of common or preferred stock dividends, a payment that may be temporarily or permanently suspended by the issuer on any instrument that is eligible for inclusion in the numerator of any minimum regulatory capital ratio, and any similar transaction that FHFA determines to be in substance a distribution of capital.

Capital plan means a written presentation of an Enterprise's capital planning strategies and capital adequacy process that includes the mandatory elements set forth in paragraph (d)(2) of this section.

Capital plan cycle means the period beginning on January 1 of a calendar year and ending on December 31 of that year.

Capital policy means an Enterprise's written principles and guidelines used for capital planning, capital issuance, capital usage and distributions, including internal capital goals; the quantitative or qualitative guidelines for capital distributions; the strategies for addressing potential capital shortfalls; and the internal governance procedures around capital policy principles and guidelines.

Common equity tier 1 capital has the same meaning as under subpart C of this part.

Effective capital distribution limitations means any limitations on capital distributions established by FHFA by order or regulation, provided that, for any limitations based on risk-weighted assets, such limitations must be calculated using the standardized approach, as set forth in subpart D of this part.

Final planned capital distributions means the planned capital distributions included in a capital plan that include the adjustments made pursuant to paragraph (g) of this section, if any.

Internal baseline scenario means a scenario that reflects the Enterprise's expectation of the economic and financial outlook, including expectations related to the Enterprise's capital adequacy and financial condition.

Internal stress scenario means a scenario designed by an Enterprise that stresses the specific vulnerabilities of the Enterprise's risk profile and operations, including those related to the Enterprise's capital adequacy and financial condition.

Planning horizon means the period of at least nine consecutive quarters for the FHFA scenarios and at least five years for the Internal scenarios, beginning with the quarter preceding the quarter in which the Enterprise submits its capital plan, over which the relevant projections extend, unless otherwise directed by FHFA.

Regulatory capital ratio means a capital ratio for which FHFA has established minimum requirements for the Enterprise by regulation or order, including, as applicable, the Enterprise's regulatory capital ratios calculated under subpart B of this part; except that the Enterprise shall not use the advanced approaches to calculate its regulatory capital ratios.

Severely adverse scenario has the same meaning as under 12 CFR part 1238.

Stability capital buffer has the same meaning as under subpart G of this part.

Stress capital buffer means the amount calculated under paragraph (e) of this section.

Supervisory stress test means a stress test conducted by FHFA using a severely adverse scenario and the assumptions contained in 12 CFR part 1238.

(d) *Capital planning requirements and procedures*—(1) *Annual capital planning.* (i) An Enterprise must develop and maintain a capital plan.

(ii) An Enterprise must submit its complete capital plan to FHFA by May 20 of each calendar year, or such later date as directed by FHFA.

(iii) The Enterprise's board of directors or a designated committee thereof must at least annually and prior to submission of the capital plan under paragraph (d)(1)(ii) of this section:

(A) Review the robustness of the Enterprise's process for assessing capital adequacy;

(B) Ensure that any deficiencies in the Enterprise's process for assessing capital adequacy are appropriately remedied; and

(C) Approve the Enterprise's capital plan.

(2) *Mandatory elements of capital plan.* A capital plan must contain at least the following elements:

(i) An assessment of the expected uses and sources of capital over the planning horizon that reflects the Enterprise's size, complexity, risk profile, and scope of operations, assuming both expected and stressful conditions, including:

(A) Estimates of projected revenues, expenses, losses, reserves, and pro forma capital levels, including regulatory capital ratios, and any additional capital measures deemed relevant by the Enterprise, over the planning horizon under a range of scenarios, including the Internal baseline scenario and at least one Internal stress scenario, as well as any additional scenarios that FHFA may provide the Enterprise after giving notice to the Enterprise;

(B) A discussion of the results of any stress test required by law or regulation, and an explanation of how the capital plan takes these results into account; and

(C) A description of all planned capital actions over the planning horizon. Planned capital actions must be consistent with any effective capital distribution limitations, except as may be adjusted pursuant to paragraph (g) of this section. In determining whether an

Enterprise's planned capital distributions are consistent with effective capital distribution limitations, an Enterprise must assume that:

(*1*) Any countercyclical capital buffer amount currently applicable to the Enterprise remains at the same level, except that the Enterprise must reflect any increases or decreases in the countercyclical capital buffer amount that have been announced by FHFA at the times indicated by FHFA's announcement for when such increases or decreases will take effect; and

(*2*) Any stability capital buffer currently applicable to the Enterprise when the capital plan is submitted remains at the same level, except that the Enterprise must reflect any increase in its stability capital buffer pursuant to § 1240.400(c)(1), beginning in the fifth quarter of the planning horizon.

(ii) A detailed description of the Enterprise's process for assessing capital adequacy, including:

(A) A discussion of how the Enterprise will, under expected and stressful conditions, maintain capital commensurate with its risks, and maintain capital above the regulatory capital ratios;

(B) A discussion of how the Enterprise will, under expected and stressful conditions, maintain sufficient capital to continue its operations by maintaining ready access to funding, meeting its obligations to creditors and other counterparties, and continuing to serve as a credit intermediary;

(iii) The Enterprise's capital policy; and

(iv) A discussion of any expected changes to the Enterprise's business plan that are likely to have a material impact on the Enterprise's capital adequacy or liquidity.

(3) *Data collection.* Upon the request of FHFA, the Enterprise shall provide FHFA with information regarding:

(i) The Enterprise's financial condition, including its capital;

(ii) The Enterprise's structure;

(iii) Amount and risk characteristics of the Enterprise's on- and off-balance sheet exposures, including exposures within the Enterprise's trading account, other trading-related exposures (such as counterparty-credit risk exposures) or other items sensitive to changes in market factors, including, as appropriate, information about the sensitivity of positions to changes in market rates and prices;

(iv) The Enterprise's relevant policies and procedures, including risk management policies and procedures;

(v) The Enterprise's liquidity profile and management;

(vi) The loss, revenue, and expense estimation models used by the Enterprise for stress scenario analysis, including supporting documentation regarding each model's development and validation; and

(vii) Any other relevant qualitative or quantitative information requested by FHFA to facilitate review of the Enterprise's capital plan under this section.

(4) *Resubmission of a capital plan.* (i) An Enterprise must update and resubmit its capital plan to FHFA within 30 calendar days of the occurrence of one of the following events:

(A) The Enterprise determines there has been or will be a material change in the Enterprise's risk profile, financial condition, or corporate structure since the Enterprise last submitted the capital plan to FHFA; or

(B) FHFA instructs the Enterprise in writing to revise and resubmit its capital plan, as necessary to monitor risks to capital adequacy, for reasons including, but not limited to:

(*1*) The capital plan is incomplete or the capital plan, or the Enterprise's internal capital adequacy process, contains material weaknesses;

(*2*) There has been, or will likely be, a material change in the Enterprise's risk profile (including a material change in its business strategy or any risk exposure), financial condition, or corporate structure; or

(*3*) The Internal stress scenario(s) are not appropriate for the Enterprise's business model and portfolios, or changes in financial markets or the macro-economic outlook that could have a material impact on an Enterprise's risk profile and financial condition require the use of updated scenarios; or

(ii) FHFA may extend the 30-day period in paragraph (d)(4)(i) of this section for up to an additional 60 calendar days, or such longer period as FHFA determines appropriate.

(iii) Any updated capital plan must satisfy all the requirements of this section; however, an Enterprise may continue to rely on information submitted as part of a previously submitted capital plan to the extent that the information remains accurate and appropriate.

(5) *Confidential treatment of information submitted.* The confidentiality of information submitted to FHFA under this section and related materials shall be determined in accordance with applicable exemptions under the Freedom of Information Act (5 U.S.C. 552(b)) and FHFA's rule in 12 CFR part 1214—Availability of Non-Public Information.

(e) *Calculation of the stress capital buffer*—(1) *General.* FHFA will determine the stress capital buffer that applies under § 1240.11 pursuant to this paragraph (e). FHFA will calculate the Enterprise's stress capital buffer requirement annually.

(2) *Stress capital buffer calculation.* An Enterprise's stress capital buffer is equal to the Enterprise's adjusted total assets, as of the last day of the previous calendar quarter, multiplied by the greater of:

(i) The following calculation:

(A) The ratio of an Enterprise's common equity tier 1 capital to adjusted total assets, as of the final quarter of the previous capital plan cycle, unless otherwise determined by FHFA; minus

(B) The lowest projected ratio of the Enterprise's common equity tier 1 capital to adjusted total assets, in any quarter of the planning horizon under a supervisory stress test; plus

(C) The ratio of:

(*1*) The sum of the Enterprise's planned common stock dividends (expressed as a dollar amount) for each of the fourth through seventh quarters of the planning horizon; to

(*2*) The adjusted total assets of the Enterprise in the quarter in which the Enterprise had its lowest projected ratio of common equity tier 1 capital to adjusted total assets, in any quarter of the planning horizon under a supervisory stress test; and

(ii) 0.75 percent.

(3) *Recalculation of stress capital buffer.* If an Enterprise resubmits its capital plan pursuant to paragraph (d)(4) of this section, FHFA may recalculate the Enterprise's stress capital buffer. FHFA will provide notice of whether the Enterprise's stress capital buffer will be recalculated within 75 calendar days after the date on which the capital plan is resubmitted, unless FHFA provides notice to the Enterprise that it is extending the time period.

(f) *Review of capital plans by FHFA.* FHFA will consider the following factors in reviewing an Enterprise's capital plan:

(1) The comprehensiveness of the capital plan, including the extent to which the analysis underlying the capital plan captures and addresses potential risks stemming from activities across the Enterprise and the Enterprise's capital policy;

(2) The reasonableness of the Enterprise's capital plan, the assumptions and analysis underlying the capital plan, and the robustness of its capital adequacy process;

(3) Relevant supervisory information about the Enterprise and its subsidiaries;

(4) The Enterprise's regulatory and financial reports, as well as supporting data that would allow for an analysis of the Enterprise's loss, revenue, and reserve projections;

(5) The results of any stress tests conducted by the Enterprise or FHFA; and

(6) Other information requested or required by FHFA, as well as any other information relevant, or related, to the Enterprise's capital adequacy.

(g) *FHFA notice of stress capital buffer; final planned capital distributions*—(1) *Notice.* FHFA will provide an Enterprise with notice of its stress capital buffer and an explanation of the results of the supervisory stress test. Unless otherwise determined by FHFA, notice will be provided by August 15 of the calendar year in which the capital plan was submitted pursuant to paragraph (d)(1)(ii) of this section or within 90 calendar days of receiving notice that FHFA will recalculate the Enterprise's stress capital buffer pursuant to paragraph (e)(3) of this section.

(2) *Response to notice*—(i) *Request for reconsideration of stress capital buffer.* An Enterprise may request reconsideration of a stress capital buffer provided under paragraph (g)(1) of this section. To request reconsideration of a stress capital buffer, an Enterprise must submit to FHFA a request pursuant to paragraph (h) of this section.

(ii) *Adjustments to planned capital distributions.* Within two business days of receipt of notice of a stress capital buffer under paragraph (g)(1) or (h)(5) of this section, as applicable, an Enterprise must:

(A) Determine whether the planned capital distributions for the fourth through seventh quarters of the planning horizon under the Internal baseline scenario would be consistent with effective capital distribution limitations assuming the stress capital buffer provided by FHFA under paragraph (g)(1) or (h)(5) of this section, as applicable, in place of any stress capital buffer in effect; and

(*1*) If the planned capital distributions for the fourth through seventh quarters of the planning horizon under the Internal baseline scenario would not be consistent with effective capital distribution limitations assuming the stress capital buffer provided by FHFA under paragraph (g)(1) or (h)(5) of this section, as applicable, in place of any stress capital buffer in effect, the Enterprise must adjust its planned capital distributions such that its planned capital distributions would be consistent with effective capital distribution limitations assuming the stress capital buffer provided by FHFA under paragraph (g)(1) or (h)(5) of this section, as applicable, in place of any stress capital buffer in effect; or

(*2*) If the planned capital distributions for the fourth through seventh quarters of the planning horizon under the Internal baseline scenario would be consistent with effective capital distribution limitations assuming the stress capital buffer provided by FHFA under paragraph (g)(1) or (h)(5) of this section, as applicable, in place of any stress capital buffer in effect, the Enterprise may adjust its planned capital distributions. An Enterprise may not adjust its planned capital distributions to be inconsistent with the effective capital distribution limitations assuming the stress capital buffer provided by FHFA under paragraph (g)(1) or (h)(5) of this section, as applicable; and

(B) Notify FHFA of any adjustments made to planned capital distributions for the fourth through seventh quarters of the planning horizon under the Internal baseline scenario.

(3) *Final planned capital distributions.* FHFA will consider the planned capital distributions, including any adjustments made pursuant to paragraph (g)(2)(ii) of this section, to be the Enterprise's final planned capital distributions on the later of:

(i) The expiration of the time for requesting reconsideration under paragraph (i) of this section; and

(ii) The expiration of the time for adjusting planned capital distributions pursuant to paragraph (g)(2)(ii) of this section.

(4) *Effective date of final stress capital buffer.* (i) FHFA will provide an Enterprise with its final stress capital buffer and confirmation of the Enterprise's final planned capital distributions by August 31 of the calendar year that a capital plan was submitted pursuant to paragraph (d)(1)(ii) of this section, unless otherwise determined by FHFA. A stress capital buffer will not be considered final so as to be agency action subject to judicial review under 5 U.S.C. 704 during the pendency of a request for reconsideration made pursuant to paragraph (h) of this section or before the time for requesting reconsideration has expired.

(ii) Unless otherwise determined by FHFA, an Enterprise's final planned capital distributions and final stress capital buffer shall:

(A) Be effective on October 1 of the calendar year in which a capital plan was submitted pursuant to paragraph (d)(1)(ii) of this section; and

(B) Remain in effect until superseded.

(5) *Publication.* With respect to an Enterprise subject to this section, FHFA may disclose publicly any or all of the following:

(i) The stress capital buffer provided to an Enterprise under paragraph (g)(1) or (h)(5) of this section;

(ii) Adjustments made pursuant to paragraph (g)(2)(ii) of this section;

(iii) A summary of the results of the supervisory stress test; and

(iv) Other information.

(h) *Administrative remedies; request for reconsideration.* The following requirements and procedures apply to any request under this paragraph (h):

(1) *General.* To request reconsideration of a stress capital buffer, provided under paragraph (g) of this section, an Enterprise must submit a written request for reconsideration.

(2) *Timing of request.* A request for reconsideration of a stress capital buffer, provided under paragraph (g) of this section, must be received within 15 calendar days of receipt of a notice of an Enterprise's stress capital buffer.

(3) *Contents of request.* (i) A request for reconsideration must include a detailed explanation of why reconsideration should be granted (that is, why a stress capital buffer should be reconsidered). With respect to any information that was not previously provided to FHFA in the Enterprise's capital plan, the request should include an explanation of why the information should be considered.

(ii) A request for reconsideration may include a request for an informal hearing on the Enterprise's request for reconsideration.

(4) *Hearing.* (i) FHFA may, in its sole discretion, order an informal hearing if FHFA finds that a hearing is appropriate or necessary to resolve disputes regarding material issues of fact.

(ii) An informal hearing shall be held within 30 calendar days of a request, if granted, provided that FHFA may extend this period upon notice to the requesting party.

(5) *Response to request.* Within 30 calendar days of receipt of the Enterprise's request for reconsideration of its stress capital buffer submitted under paragraph (h)(2) of this section or within 30 days of the conclusion of an informal hearing conducted under paragraph (h)(4) of this section, FHFA will notify the Enterprise of its decision to affirm or modify the Enterprise's stress capital buffer, provided that FHFA may extend this period upon notice to the Enterprise.

(6) *Distributions during the pendency of a request for reconsideration.* During the pendency of FHFA's decision under paragraph (h)(5) of this section, the Enterprise may make capital distributions that are consistent with effective distribution limitations, unless prior approval is required under paragraph (i)(1) of this section.

(i) *Approval requirements for certain capital actions*—(1) *Circumstances requiring approval—resubmission of a capital plan.* Unless it receives prior approval pursuant to paragraph (i)(3) of this section, an Enterprise may not make a capital distribution (excluding any capital distribution arising from the issuance of a capital instrument eligible for inclusion in the numerator of a regulatory capital ratio) if the capital distribution would occur after the occurrence of an event requiring resubmission under paragraph (d)(4)(i)(A) or (B) of this section.

(2) *Contents of request.* A request for a capital distribution under this section must contain the following information:

(i) The Enterprise's capital plan or a discussion of changes to the Enterprise's capital plan since it was last submitted to FHFA;

(ii) The purpose of the transaction;

(iii) A description of the capital distribution, including for redemptions or repurchases of securities, the gross consideration to be paid and the terms and sources of funding for the transaction, and for dividends, the amount of the dividend(s); and

(iv) Any additional information requested by FHFA (which may include, among other things, an assessment of the Enterprise's capital adequacy under a severely adverse scenario, a revised capital plan, and supporting data).

(3) *Approval of certain capital distributions.* (i) FHFA will act on a request for prior approval of a capital distribution within 30 calendar days after the receipt of all the information required under paragraph (i)(2) of this section.

(ii) In acting on a request for prior approval of a capital distribution, FHFA will apply the considerations and principles in paragraph (f) of this section, as appropriate. In addition, FHFA may disapprove the transaction if the Enterprise does not provide all of the information required to be submitted under paragraph (i)(2) of this section.

(4) *Disapproval and hearing.* (i) FHFA will notify the Enterprise in writing of the reasons for a decision to disapprove any proposed capital distribution. Within 15 calendar days after receipt of a disapproval by FHFA, the Enterprise may submit a written request for a hearing.

(ii) FHFA may, in its sole discretion, order an informal hearing if FHFA finds that a hearing is appropriate or necessary to resolve disputes regarding material issues of fact. An informal hearing shall be held within 30 calendar days of a request, if granted, provided that FHFA may extend this period upon notice to the requesting party.

(iii) Written notice of the final decision of FHFA shall be given to the Enterprise within 60 calendar days of the conclusion of any informal hearing ordered by FHFA, provided that FHFA may extend this period upon notice to the requesting party.

(iv) While FHFA's decision is pending and until such time as FHFA approves the capital distribution at issue, the Enterprise may not make such capital distribution.

(j) *Post notice requirement.* An Enterprise must notify FHFA within 15 days of making a capital distribution if:

(1) The capital distribution was approved pursuant to paragraph (i)(3) of this section; or

(2) The dollar amount of the capital distribution will exceed the dollar amount of the Enterprise's final planned capital distributions, as measured on an aggregate basis beginning in the fourth quarter of the planning horizon through the quarter at issue.

Sandra L. Thompson,

Acting Director, Federal Housing Finance Agency.

[FR Doc. 2021–27589 Filed 12–23–21; 8:45 am]

BILLING CODE 8070–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–1076; Project Identifier MCAI–2021–00560–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 all Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. This proposed AD was prompted by reports of in-service findings of corrosion on the flange of the main landing gear (MLG) lower spindle pin. This proposed AD would require repetitive inspections of the left and right MLG lower spindle pins to detect corrosion, and applicable repair or replacement if necessary, as specified in a Transport Canada Civil Aviation (TCCA) AD, which is proposed for incorporation by reference. 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 February 10, 2022.

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 *https://www.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.

For material that will be incorporated by reference (IBR) in this AD, contact TCCA, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario, K1A 0N5, Canada; telephone 888–663–3639; email *AD-CN@tc.gc.ca;* internet *https://tc.canada.ca/en/aviation.* You may view this IBR 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. It is also available in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1076.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1076; 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.

FOR FURTHER INFORMATION CONTACT: Chirayu Gupta, Aerospace Engineer, Mechanical Systems and Administrative

Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531; 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–2021–1076; Project Identifier MCAI–2021–00560–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 *https://www.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 Chirayu Gupta, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531; 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

TCCA, which is the aviation authority for Canada, has issued TCCA AD CF–2021–22, issued July 5, 2021 (TCCA AD CF–2021–22) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for all Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. TCCA AD CF–2021–22 superseded TCCA AD CF–2021–18, dated May 6, 2021, to correct an error in a compliance time.

This proposed AD was prompted by reports of in-service findings of corrosion on the flange of the MLG lower spindle pin. Investigation revealed that micro-fretting of the anti-rotation washer at the spindle pin flange surface causes abrasion of the protective coating, and leaves the flange area susceptible to corrosion. The MLG lower spindle pin is a principal structural element (PSE); if the corrosion progresses from the flange to the adjacent radius area, it can lead to low cycle fatigue (LCF) cracking. The FAA is proposing this AD to address corrosion and subsequent cracking of the MLG lower spindle pin, which could result in failure of the pin, and consequent collapse of the MLG. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

TCCA AD CF–2021–22 specifies procedures for repetitive inspections (including visual and liquid penetrant inspections and nondestructive tests) of the left and right MLG lower spindle pins for corrosion, and applicable repair or replacement of the MLG lower spindle pin. 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 the **ADDRESSES** section.

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 the 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 TCCA AD CF–2021–22 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 TCCA AD CF–2021–22 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with TCCA AD CF–2021–22 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 TCCA AD CF–2021–22 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 ''Corrective Actions'' in TCCA AD CF–2021–22. Service information required by TCCA AD CF–2021–22 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1076 after the FAA final rule is published.

Interim Action

The FAA considers this proposed AD interim action. If final action is later identified, the FAA might consider further rulemaking then.

Costs of Compliance

The FAA estimates that this proposed AD would affect 51 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 25 work-hours × $85 per hour = $2,125	$0	Up to $2,125	Up to $108,375 per inspection cycle.

The FAA estimates the following costs to do any necessary on-condition actions that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need these on-condition actions:

ESTIMATED COSTS OF ON-CONDITION ACTIONS *

Labor cost	Parts cost	Cost per product
Up to 3 work-hours × $85 per hour = $255	Up to $33,038	Up to $33,293.

* Table does not include estimated costs for reporting.

The FAA estimates that it would take 1 work-hour per product to comply with the on-condition reporting requirement in this proposed AD. The average labor rate is $85 per hour. Based on these figures, the FAA estimates the cost of reporting the inspection results on U.S. operators to be $85 per product.

According to the manufacturer, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all known costs in the cost estimate.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to take approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

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–2021–1076; Project Identifier MCAI–2021–00560–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by February 10, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all 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.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing Gear.

(e) Unsafe Condition

This AD was prompted by reports of in-service findings of corrosion on the flange of the main landing gear (MLG) lower spindle pin. The FAA is issuing this AD to address corrosion and subsequent cracking of the MLG lower spindle pin, which could result in failure of the pin, and consequent collapse of the MLG.

(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 Civil Aviation (TCCA) AD CF–2021–22, issued July 5, 2021 (TCCA AD CF–2021–22).

(h) Exceptions to TCCA AD 2021–22

(1) Where TCCA AD CF–2021–22 refers to May 20, 2021, the effective date of TCCA AD CF–2021–18, this AD requires using the effective date of this AD.

(2) Where the service information identified in TCCA AD CF–2021–22 specifies to report inspection results, for this AD, report only positive findings of the first four inspections at the applicable time specified in paragraph (h)(2)(i) or (ii) of this AD.

(i) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(ii) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO 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 certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7300; fax: 516–794–5531. 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, New York ACO Branch, FAA; or TCCA; or Airbus Canada Limited Partnership's TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Related Information

(1) For TCCA AD CF–2021–22, contact TCCA, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *AD-CN@tc.gc.ca;* internet *https://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. This material may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1076.

(2) For more information about this AD, contact Chirayu Gupta, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

Issued on December 16, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–27833 Filed 12–23–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–1075; Project Identifier MCAI–2021–00856–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 supersede Airworthiness Directive (AD) 2020–26–01, which applies to all Airbus SAS Model A318–111, –112, –121, and –122 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; and Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes. AD 2020–26–01 requires repetitive general visual inspections of the affected main landing gear (MLG) sliding tubes for cracks and replacement if necessary. Since the FAA issued AD 2020–26–01, additional parts and additional airplane models have been identified that may also have been subject to an improper overhaul and are therefore unsafe. This proposed AD would require repetitive general visual inspections of the affected MLG sliding tubes (both retained affected parts and additional affected parts) for cracks and replacement if necessary, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. This proposed AD would also add airplanes to the applicability. 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 February 10, 2022.

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 *https://www.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:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For material that will be incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR 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. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1075.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1075; 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, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

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–2021–1075; Project Identifier MCAI–2021–00856–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 the 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 *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

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 Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

The FAA issued AD 2020–26–01, Amendment 39–21356 (85 FR 82299, December 18, 2020) (AD 2020–26–01), which applies to all Airbus SAS Model A318–111, –112, –121, and –122 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; and Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes. AD 2020–26–01 requires repetitive general visual inspections of the MLG sliding tubes for cracks, and replacement if necessary. The FAA issued AD 2020–26–01 to address cracks on the MLG sliding tubes, which could cause MLG sliding tube fracture, and could result in the MLG collapsing, damage to the airplane, and injury to occupants.

Actions Since AD 2020–26–01 Was Issued

Since the FAA issued AD 2020–26–01, additional parts and additional airplane models have been identified that may also have been subject to an improper overhaul and are therefore unsafe.

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0175, dated July 22, 2021; corrected July 23, 2021 (EASA AD 2021–0175) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for all Airbus SAS A318–111, A318–112, A318–121, A318–122, A319–111, A319–112, A319–113, A319–114, A319–115, A319–131, A319–132, A319–133, A320–211, A320–212, A320–214, A320–215, A320–216, A320–231, A320–232, A320–233, A321–111, A321–112, A321–131, A321–211, A321–212, A321–213, A321–231, and A321–232 airplanes. EASA AD 2021–0175 supersedes EASA AD 2020–0258 (which corresponds to FAA AD 2020–26–01). Model A320–215 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this proposed AD therefore does not include those airplanes in the applicability.

This proposed AD was prompted by reports of cracks found on additional MLG sliding tubes that may have been subject to the same improperly performed magnetic particle inspection as the MLG sliding tubes identified in AD 2020–26–01. The FAA is proposing this AD to address cracks on the MLG sliding tubes, which could cause MLG sliding tube fracture, and could result in the MLG collapsing, damage to the airplane, and injury to occupants. See the MCAI for additional background information.

Explanation of Retained Requirements

Although this proposed AD does not explicitly restate the requirements of AD 2020–26–01, this proposed AD would retain all of the requirements of AD 2020–26–01. Those requirements are referenced in EASA AD 2021–0175, which, in turn, is referenced in paragraph (g) of this proposed AD.

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0175 describes procedures for repetitive general visual inspections of the MLG sliding tubes for cracks, and replacement if necessary. EASA AD 2021–0175 also describes terminating actions for the repetitive inspections of affected MLG sliding tubes by either overhauling an affected MLG sliding tube or replacing an affected MLG sliding tube with an MLG sliding tube that is not affected.

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 the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

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 the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI referenced above. The FAA is proposing this AD because the FAA evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in EASA AD 2021–0175 described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this 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 2021–0175 by reference in the FAA final rule. This

proposed AD would, therefore, require compliance with EASA AD 2021–0175 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 2021–0175 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 2021–0175. Service information required by EASA AD 2021–0175 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1075 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD affects 1,524 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2020–26–01	2 work-hours × $85 per hour = $170	$0	$170	$259,080
New proposed actions	2 work-hours × $85 per hour = $170	0	170	259,080

The FAA estimates the following costs to do any necessary on-condition actions that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need these on-condition actions:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
19 work-hours × $85 per hour = $1,615	$185	$1,800

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) 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 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:

■ a. Removing Airworthiness Directive (AD) 2020–26–01, Amendment 39–21356 (85 FR 82299, December 18, 2020); and

■ b. Adding the following new AD:

Airbus SAS: Docket No. FAA–2021–1075; Project Identifier MCAI–2021–00856–T.

(a) Comments Due Date

The FAA must receive comments by February 10, 2022.

(b) Affected Airworthiness Directives (ADs)

This AD replaces AD 2020–26–01, Amendment 39–21356 (85 FR 82299, December 18, 2020) (AD 2020–26–01).

(c) Applicability

This AD applies to all Airbus SAS airplanes identified in paragraphs (c)(1) through (4) of this AD, certificated in any category.

(1) Model A318–111, –112, –121, and –122 airplanes.

(2) Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(3) Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes.

(4) Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing gear.

(e) Reason

This AD was prompted by reports of cracks found on main landing gear (MLG) sliding tubes that may have been subject to improperly performed magnetic particle inspection. The FAA is issuing this AD to address cracks on the MLG sliding tubes, which could cause MLG sliding tube fracture, and could result in the MLG collapsing, damage to the airplane, and injury to occupants.

(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, European Union Aviation Safety Agency (EASA) AD 2021–0175, dated July 22, 2021; corrected July 23, 2021 (EASA AD 2021–0175).

(h) Exceptions to EASA AD 2021–0175

(1) Where EASA AD 2021–0175 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2021–0175 refers to July 10, 2018 (the effective date of EASA AD 2018–0136, dated June 26, 2018), this AD requires using April 9, 2019 (the effective date of AD 2019–03–18, Amendment 39–19570 (84 FR 7804, March 5, 2019).

(3) Where EASA AD 2021–0175 refers to December 2, 2020 (the effective date of EASA AD 2020–0258, dated November 18, 2020; corrected November 19. 2020), this AD requires using January 4, 2021 (the effective date of AD 2020–26–01).

(4) Where paragraph (1) of EASA AD 2021–0175 specifies compliance times to do the initial inspection, for this AD, the initial inspection must be done within the applicable compliance time specified in paragraph (1) of EASA AD 2021–0175, or within 30 days after the effective date of this AD, whichever occurs later.

(5) The ''Remarks'' section of EASA AD 2021–0175 does not apply to this AD.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2021–0175 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, 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 Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (k)(2) 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, Large Aircraft Section, 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):* For any service information referenced in EASA AD 2021–0175 that contains RC procedures and tests: Except as required by paragraph (j)(2) of this AD and as specified in paragraph (i) of this AD, RC 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.

(k) Related Information

(1) For information about EASA AD 2021–0175, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* Internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* 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. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1075.

(2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

Issued on December 16, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–27834 Filed 12–23–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1147; Airspace Docket No. 21–AGL–37]

RIN 2120–AA66

Proposed Establishment of Class E Airspace; Pembina, ND

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Pembina, ND. The FAA is proposing this action due to an airspace review conducted as part of the decommissioning of the Humbolt very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program. The geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database.

DATES: Comments must be received on or before February 10, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2021–1147/Airspace Docket No. 21–AGL–37 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority

described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Pembina Municipal Airport, Pembina, ND, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2021–1147/Airspace Docket No. 21–AGL–37.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov*. Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/*.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by amending the Class E airspace extending upward from 700 feet above the surface to within a 6.4-mile (increased from a 6.2-mile) radius of Pembina Municipal Airport, Pembina, ND; removing the Humbolt VORTAC and associated extension from the airspace legal description; removing Grand Forks AFB, Devils Lake VOR/DME, and the airspace extending upward from 1,200 feet above the surface from the airspace legal description as it is covered by the Class E airspace extending upward from 1,200 feet above the surface over the State of North Dakota, is redundant, and no longer needed; adding exclusionary language north of latitude 49°00′00″ N that prevents the airspace from extending into Canadian airspace; and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is due to an airspace review conducted as part of the decommissioning of the Humbolt VOR, which provided navigation information for the instrument procedures at this airport, as part of the VOR MON Program.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL ND E5 Pembina, ND [Amended]

Pembina Municipal Airport, ND

(Lat. 48°56′33″ N, long. 97°14′26″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Pembina Municipal Airport, excluding that airspace north of lat. 49°00′00″ N.

Issued in Fort Worth, Texas, on December 20, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2021–27917 Filed 12–23–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1145; Airspace Docket No. 21–AGL–35]

RIN 2120–AA66

Proposed Establishment of Class E Airspace; Multiple Michigan Towns

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E airspace at Cadillac, MI; Ludington, MI; and Manistee, MI. The FAA is proposing this action due to airspace reviews conducted as part of the decommissioning of the Manistee very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program. The names and geographic coordinates of various airports would also be updated to coincide with the FAA's aeronautical database.

DATES: Comments must be received on or before February 10, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2021–1145/Airspace Docket No. 21–AGL–35 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Wexford County Airport, Cadillac, MI; Mason County Airport, Ludington, MI; and Manistee County/Blacker Airport, Manistee, MI, to support instrument flight rule operations at these airports.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2021–1145/Airspace Docket No. 21–AGL–35.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by:

Amending the Class E airspace extending upward from 700 feet above the surface to within a 6.6-mile (decreased from a 6.7-mile) radius of Wexford County Airport, Cadillac, MI;

and removing the city associated with the airport in the header to comply with changes to FAA Order JO 7400.2N, Procedures for Handling Airspace Matters;

Amending the Class E airspace extending upward from 700 feet above the surface to within a 6.6-mile (decreased from a 7-mile) radius of Mason County Airport, Ludington, MI; removing the city associated with the airport in the header to comply with changes to FAA Order JO 7400.2N; and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database;

And amending the Class E airspace extending upward from 700 feet above the surface to within a 6.6-mile (decreased from a 7-mile) radius of Manistee County/Blacker Airport, Manistee, MI; removing the Manistee VOR/DME and associated extensions from the airspace legal description; adding an extension 6.5 miles north and 5.3 miles south of the 091° bearing from the Manistee County/Blacker Airport: RWY 28–LOC extending from the 6.6-mile radius of the airport to 16.5 miles east of the Manistee County/Blacker Airport: RWY 28–LOC; adding and extension 2.2 miles each side of the 271° bearing from the airport extending from the 6.6-mile radius of the airport to 10 miles west of the airport; and updating the airport name (previously Manistee County—Blacker Airport) to coincide with the FAA's aeronautical database.

This action is due to airspace reviews conducted as part of the decommissioning of the Manistee VOR, which provided navigation information for the instrument procedures at these airports, as part of the VOR MON Program.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL MI E5 Cadillac, MI [Amended]

Wexford County Airport, MI
(Lat. 44°16′31″ N, long. 85°25′08″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of the Wexford County Airport.

* * * * *

AGL MI E5 Ludington, MI [Amended]

Mason County Airport, MI
(Lat. 43°57′45″ N, long. 86°24′29″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Mason County Airport.

* * * * *

AGL MI E5 Manistee, MI [Amended]

Manistee County/Blacker Airport, MI
(Lat. 44°16′21″ N, long. 86°14′49″ W)
Manistee County/Blacker Airport: RWY 28–LOC
(Lat. 44°16′22″ N, long. 86°15′31″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of the Manistee County/Blacker Airport, and within 6.5 miles north and 5.3 miles south of the 091° bearing from the Manistee County/Blacker Airport: RWY 28–LOC extending from the 6.6-mile radius of the airport to 16.5 miles east of the Manistee County/Blacker Airport: RWY 28–LOC, and within 2.2 miles each side of the 271° bearing from the airport extending from the 6.6-mile radius of the airport to 10 miles west of the airport.

Issued in Fort Worth, Texas, on December 20, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2021–27920 Filed 12–23–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1146; Airspace Docket No. 21–AGL–36]

RIN 2120–AA66

Proposed Establishment of Class E Airspace; Hallock, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E airspace at Hallock, MN. The FAA is proposing this action due to an airspace review conducted as part of the decommissioning of the Humbolt very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program.

DATES: Comments must be received on or before February 10, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2021–1146/Airspace Docket No. 21–AGL–36

at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Hallock Municipal Airport, Hallock, MN, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2021–1146/Airspace Docket No. 21–AGL–36.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by amending the Class E airspace extending upward from 700 feet above the surface at Hallock Municipal Airport, Hallock, MN, by removing the extension to the southeast of the airport as it is no longer needed.

This action is due to airspace reviews conducted as part of the decommissioning of the Humbolt VOR, which provided navigation information for the instrument procedures at these airports, as part of the VOR MON Program.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL MN E5 Hallock, MN [Amended]

Hallock Municipal Airport, MN
(Lat. 48°45′10″ N, long. 96°56′35″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Hallock Municipal Airport.

Issued in Fort Worth, Texas, on December 20, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2021–27916 Filed 12–23–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1021; Airspace Docket No. 21–ASO–9]

RIN 2120–AA66

Proposed Amendment and Removal of Air Traffic Service (ATS) Routes; Eastern United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend three jet routes and remove one jet route in the eastern United States. This action is associated with the decommissioning of the Atlanta VHF Omnidirectional Range and Tactical Air Navigation (VORTAC) system in support of the VHF Omnidirectional Range (VOR) Minimum Operational Network (MON) to improve the efficiency of the National Airspace System (NAS) and reduce dependency on ground-based navigational systems.

DATES: Comments must be received on or before February 10, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1(800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2021–1021; Airspace Docket No. 21–ASO–9 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the route structure as necessary to preserve the safe and efficient flow of air traffic within the NAS.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2021–1021; Airspace Docket No. 21–ASO–9) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2021–1021; Airspace Docket No. 21–ASO–9.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during

normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to amend three and remove one jet routes in the eastern United States. This action is associated with the planned decommissioning of the Atlanta VORTAC and the VOR MON program by amending and removing certain jet route segments that are being replaced by area navigation routing. Additionally, the proposed jet route changes would reduce aeronautical chart clutter by removing unneeded route segments.

The proposed route changes are as follows:

J–4: J–4 currently extends between the Los Angeles, CA, (LAX) VORTAC, and the Colliers, SC, (IRQ) VORTAC. The FAA proposes to remove the latter segment from the Meridian, MS, (MEI) VORTAC to the Colliers VORTAC. As proposed, the amendment route would extend between the Los Angeles, CA, (LAX) VORTAC and the Magnolia, MS, (MHZ) VORTAC.

J–45: J–45 currently extends between the Atlanta, GA, VORTAC, and the Aberdeen, SD, (ABR) VOR/Distance Measuring Equipment (VOR/DME). The FAA proposes to remove the Atlanta, GA, (ATL) VORTAC in the initial segment. As proposed, the amendment route would extend between the Nashville, TN, (BNA) VORTAC, and the Aberdeen, SD, (ABR) VOR/DME.

J–89: J–89 currently extends between the Atlanta, GA, VORTAC, and the Winnipeg, MB, Canada, (YWG) VORTAC. The FAA proposes to remove the Atlanta, GA, (ATL) VORTAC in the initial segment. As proposed, the amendment route would extend between the Louisville, KY, (IIU) VORTAC, and the Winnipeg, MB, Canada, (YWG) VORTAC. The portion within Canada is excluded.

J–239: J–239 currently extends between the Atlanta, GA, (ATL) VORTAC and the Meridian, MS, (MEI) VORTAC. The FAA proposes to remove the entire route.

Jet routes are published in paragraph 2004 of FAA Order JO 7400.11F dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The jet routes listed in this document would be subsequently amended in, or removed, respectively, from FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 2004 Jet Routes.

* * * * *

J–4 [Amended]

From Los Angeles, CA, via INT Los Angeles 083° and Twentynine Palms, CA, 269° radials; Twentynine Palms; Parker, CA; Buckeye, AZ; San Simon, AZ; Newman, TX; Wink, TX; Abilene, TX; Ranger, TX; Belcher, LA; to Magnolia, MS.

* * * * *

J–45 [Amended]

From Nashville, TN; St Louis, MO; Kirksville, MO; Des Moines, IA; Sioux Falls, SD; to Aberdeen, SD.

* * * * *

J–89 [Amended]

From Louisville, KY; Boiler, IN; Northbrook, IL; Badger, WI; Duluth, MN; to Winnipeg, MB, Canada. The portion within Canada is excluded.

* * * * *

J–239 [Removed]

* * * * *

Issued in Washington, DC, on December 15, 2021.

Margaret C. Flategraff,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2021–27831 Filed 12–23–21; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Part 1

[File No. R207005]

Petition for Rulemaking by Accountable Tech

AGENCY: Federal Trade Commission.

ACTION: Receipt of petition; request for comment.

SUMMARY: Please take notice that the Federal Trade Commission (''Commission'') received a petition for rulemaking from Accountable Tech and has published that petition online at *https://www.regulations.gov.* This petition requests promulgation of regulations to prohibit surveillance advertising. The Commission invites written comments concerning the petition. Publication of this petition is

pursuant to the Commission's Rules of Practice and Procedure, and does not affect the legal status of the petition or its final disposition.

DATES: Comments must identify the petition docket number and be filed by January 26, 2022.

ADDRESSES: You may view the petition, identified by docket number FTC–2021–0070, and submit written comments concerning its merits by using the Federal eRulemaking Portal at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit sensitive or confidential information. You may read background documents or comments received at *https://www.regulations.gov* at any time.

FOR FURTHER INFORMATION CONTACT: Daniel R. Freer, 202–326–2663, Office of the Secretary, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 18(a)(1)(B) of the Federal Trade Commission Act, 15 U.S.C. 57a(1)(B), and FTC Rule 1.31(f), 16 CFR 1.31(f), notice is hereby given that the above-captioned petition has been filed with the Secretary of the Commission and has been placed on the public record for a period of thirty (30) days. Any person may submit comments in support of or in opposition to the petition. All timely and responsive comments submitted in connection with this petition will become part of the public record. The Commission will not consider the petition's merits until after the comment period closes.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2).

Authority: 15 U.S.C. 46; 15 U.S.C. 57a; 5 U.S.C. 601 note.

April J. Tabor,

Secretary.

[FR Doc. 2021–27436 Filed 12–23–21; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

16 CFR Part 1

[File No. R207006]

Petition for Rulemaking by Institute for Policy Integrity

AGENCY: Federal Trade Commission.

ACTION: Receipt of petition; request for comment.

SUMMARY: Please take notice that the Federal Trade Commission (''Commission'') received a petition for rulemaking from Institute for Policy Integrity and has published that petition online at *https://www.regulations.gov.* This petition requests promulgation of regulations to address the practice of drip pricing. The Commission invites written comments concerning the petition. Publication of this petition is pursuant to the Commission's Rules of Practice and Procedure and does not affect the legal status of the petition or its final disposition.

DATES: Comments must identify the petition docket number and be filed by January 26, 2022.

ADDRESSES: You may view the petition, identified by docket number FTC–2021–0074, and submit written comments concerning its merits by using the Federal eRulemaking Portal at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit sensitive or confidential information. You may read background documents or comments received at *https://www.regulations.gov* at any time.

FOR FURTHER INFORMATION CONTACT: Daniel Freer (phone: 202–326–2663, email: *dfreer@ftc.gov*), Office of the Secretary, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 18(a)(1)(B) of the Federal Trade Commission Act, 15 U.S.C. 57a(1)(B), and FTC Rule 1.31(f), 16 CFR 1.31(f), notice is hereby given that the above-captioned petition has been filed with the Secretary of the Commission and has been placed on the public record for a period of thirty (30) days. Any person may submit comments in support of or in opposition to the petition. All timely and responsive comments submitted in connection with this petition will become part of the public record.

The Commission will not consider the petition's merits until after the comment period closes. It may grant or deny the petition in whole or in part, and it may deem the petition insufficient to warrant commencement of a rulemaking proceeding. The purpose of this document is to facilitate public comment on the petition to aid the Commission in determining what, if any, action to take regarding the request contained in the petition. This document is not intended to start, stop, cancel, or otherwise affect rulemaking proceedings in any way.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2).

Authority: 15 U.S.C. 46; 15 U.S.C. 57a; 5 U.S.C. 601 note.

April J. Tabor,

Secretary.

[FR Doc. 2021–27435 Filed 12–23–21; 8:45 am]

BILLING CODE 6750–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2005–0155; FRL–8391–02–OAR]

RIN 2060–AV44

National Perchloroethylene Air Emission Standards for Dry Cleaning Facilities Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is proposing amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for dry cleaning facilities using perchloroethylene (PCE) as the cleaning solvent (PCE Dry Cleaning NESHAP). The proposed amendments address the results of the technology review for the PCE Dry Cleaning NESHAP, in accordance with section 112 of the Clean Air Act (CAA). Based on the findings of the technology review, the EPA proposes to add provisions to the rule which will require all dry-to-dry machines at existing major and area sources to have both refrigerated condensers and carbon adsorbers as secondary controls.

DATES: Comments must be received on or before February 10, 2022.

Public hearing: If anyone contacts us requesting a public hearing on or before January 11, 2022, we will hold a virtual public hearing. See **SUPPLEMENTARY INFORMATION** for information on requesting and registering for a public hearing.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OAR–2005–0155, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Email: a-and-r-docket@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2005–0155 in the subject line of the message.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–OAR–2005–0155.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA–HQ–OAR–2005–0155, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand/Courier Delivery:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday (except Federal holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are open to the public by appointment only to reduce the risk of transmitting COVID–19. Our Docket Center staff also continues to provide remote customer service via email, phone, and webform. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact Brian Storey, Sector Policies and Programs Division (Mail Code D243–04), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–1103; fax number: (919) 541–4991; and email address: *brian.storey@epa.gov.*

SUPPLEMENTARY INFORMATION:

Participation in virtual public hearing. Please note that because of current Centers for Disease Control and Prevention (CDC) recommendations, as well as state and local orders for social distancing to limit the spread of COVID–19, the EPA cannot hold in-person public meetings at this time.

To request a virtual public hearing, contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov.* If requested, the virtual hearing will be held on January 11, 2022. The hearing will convene at 9:00 a.m. Eastern Time (ET) and will conclude at 3:00 p.m. ET. The EPA may close a session 15 minutes after the last pre-registered speaker has testified if there are no additional speakers. The EPA will announce further details at *https://www.epa.gov/stationary-sources-air-pollution/dry-cleaning-facilities-national-perchloroethylene-air-emission.*

If a public hearing is requested, the EPA will begin pre-registering speakers for the hearing upon publication of this document in the **Federal Register**. To register to speak at the virtual hearing, please use the online registration form available at *https://www.epa.gov/stationary-sources-air-pollution/dry-cleaning-facilities-national-perchloroethylene-air-emission* or contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov.* The last day to pre-register to speak at the hearing will be January 10, 2022. Prior to the hearing, the EPA will post a general agenda that will list pre-registered speakers in approximate order at: *https://www.epa.gov/stationary-sources-air-pollution/dry-cleaning-facilities-national-perchloroethylene-air-emission.*

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearings to run either ahead of schedule or behind schedule.

Each commenter will have 5 minutes to provide oral testimony. The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically (via email) by emailing it to *brian.storey@epa.gov.* The EPA also recommends submitting the text of your oral testimony as written comments to the rulemaking docket.

The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral testimony and supporting information presented at the public hearing.

Please note that any updates made to any aspect of the hearing will be posted online at *https://www.epa.gov/stationary-sources-air-pollution/dry-cleaning-facilities-national-perchloroethylene-air-emission.* While the EPA expects the hearing to go forward as set forth above, please monitor our website or contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov* to determine if there are any updates. The EPA does not intend to publish a document in the **Federal Register** announcing updates.

If you require the services of a translator or special accommodation such as audio description, please pre-register for the hearing with the public hearing team and describe your needs by January 3, 2022. The EPA may not be able to arrange accommodations without advanced notice.

Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OAR–2005–0155. All documents in the docket are listed in *https://www.regulations.gov/.* Although listed, 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. With the exception of such material, publicly available docket materials are available electronically in *Regulations.gov.*

Instructions. Direct your comments to Docket ID No. EPA–HQ–OAR–2005–0155. The EPA's policy is that all

comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov/,* including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit electronically any information that you consider to be CBI or other information whose disclosure is restricted by statute. This type of information should be submitted by mail as discussed below.

The EPA may publish any comment received to its public docket. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

The *https://www.regulations.gov/* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov/,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.*

Due to public health concerns related to COVID–19, the Docket Center and Reading Room are open to the public by appointment only. Our Docket Center staff also continues to provide remote customer service via email, phone, and webform. Hand deliveries or couriers will be received by scheduled appointment only. For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.*

The EPA continues to carefully and continuously monitor information from the CDC, local area health departments, and our federal partners so that we can respond rapidly as conditions change regarding COVID–19.

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov/* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2. Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA–HQ–OAR–2005–0155. Note that written comments containing CBI and submitted by mail may be delayed and no hand deliveries will be accepted.

Preamble acronyms and abbreviations. Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, it is intended to refer to the EPA. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

CAA Clean Air Act
CBI Confidential Business Information
CDC Center for Disease Control
CFR Code of Federal Regulations
ECHO Enforcement and Compliance History Online
EPA Environmental Protection Agency
EJ environmental justice
FR Federal Register
GACT generally available control technology
HAP hazardous air pollutant(s)
LDAR leak detection and repair
MACT maximum achievable control technology
NAICS North American Industry Classification System
NESHAP national emission standards for hazardous air pollutants
NTTAA National Technology Transfer and Advancement Act
OAQPS Office of Air Quality Planning and Standards
OECA Office of Enforcement and Compliance Assurance
OMB Office of Management and Budget
ORCR Office of Resource Conservation and Recovery
PCE perchloroethylene
ppm parts per million
PRA Paperwork Reduction Act
RBLC RACT/BACT/LAER Clearinghouse
RCRA Resource Conservation and Recovery Act
RFA Regulatory Flexibility Act
SBA Small Business Administration
SBEAP Small Business Environmental Assistance Program
tpy tons per year
TTN Technology Transfer Network
UMRA Unfunded Mandate Reform Act

Organization of this document. The information in this preamble is organized as follows:

I. General Information

A. Does this action apply to me?

The standards in 40 CFR part 63, subpart M, apply to industrial and commercial dry cleaning facilities that use PCE. The North American Industry Classification System (NAICS) codes applicable to 40 CFR part 63, subpart M, are 812310 (coin-operated laundries and dry cleaners), 812320 (dry cleaning and laundry services other than coin-operated services), and 812332 (industrial launderers). This list of categories and NAICS codes is not intended to be exhaustive, but rather provides a guide for readers regarding the entities that this proposed action are likely to affect.

As defined in the *Initial List of Categories of Sources Under Section 112(c)(1) of the Clean Air Act Amendments of 1990* (see 57 FR 31576, July 16, 1992) and *Documentation for Developing the Initial Source Category List, Final Report* (*see* EPA–450/3–91–030, July 1992), the PCE dry cleaning source categories include any facility engaged in cleaning soiled apparel, leather, and other fine goods. These are usually small independently operated neighborhood shops, franchise shops, and small specialty shops. The source categories only include facilities that use PCE as a cleaning agent.

Federal, state, local, and tribal government entities would not be affected by this proposed action.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this action is available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at *https://www.epa.gov/dry-cleaning-facilities-national-perchloroethylene-air-emission.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the proposal and key technical documents at this same website.

A redline version of the regulatory language that incorporates the proposed changes is available in the docket for this action (Docket ID No. EPA–HQ–OAR–2005–0155).

II. Background

A. What is the statutory authority for this action?

The statutory authority for this action is provided by sections 112 and 301 of the Clean Air Act (CAA), as amended (42 U.S.C. 7401 *et seq.*). Section 112 of the CAA establishes a two-stage regulatory process to develop standards for emissions of hazardous air pollutants (HAP) from stationary sources. Generally, the first stage involves establishing technology-based standards and the second stage involves evaluating those standards that are based on maximum achievable control technology (MACT) to determine whether additional standards are needed to address any remaining risk associated with HAP emissions. This second stage is commonly referred to as the ''residual risk review.'' In addition to the residual risk review, the CAA also requires the EPA to review MACT and generally available control technology (GACT) standards set under CAA section 112 every 8 years and revise the standards as necessary taking into account developments in practices, processes, or control technologies. This review is commonly referred to as the ''technology review,'' and is the subject of this proposal. The discussion that follows identifies the most relevant statutory sections and briefly explains the contours of the methodology used to implement these statutory requirements. A more comprehensive discussion appears in the document titled *CAA Section 112 Risk and Technology Reviews: Statutory Authority and Methodology,* in the docket for this rulemaking.

In the first stage of the CAA section 112 standard setting process, the EPA promulgates technology-based standards under CAA section 112(d) for categories of sources identified as emitting one or more of the HAP listed in CAA section 112(b). Sources of HAP emissions are either major sources or area sources, and CAA section 112 establishes different requirements for major source standards and area source standards. ''Major sources'' are those that emit or have the potential to emit 10 tons per year (tpy) or more of a single HAP or 25 tpy or more of any combination of HAP. All other sources are ''area sources.'' For major sources, CAA section 112(d)(2) provides that the technology-based NESHAP must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). These standards are commonly referred to as MACT standards. CAA section 112(d)(3) also establishes a minimum control level for MACT standards, known as the MACT ''floor.'' In certain instances, as provided in CAA section 112(h), the EPA may set work practice standards in lieu of numerical emission standards. The EPA must also consider control options that are more stringent than the floor. Standards more stringent than the floor are commonly referred to as ''beyond-the-floor'' standards. For area sources, CAA section 112(d)(5) allows the EPA to set standards based on GACT standards in lieu of MACT standards. For categories of major sources and any area source categories subject to MACT standards, the second stage in standard-setting focuses on identifying and addressing any remaining (*i.e.,* ''residual'') risk pursuant to CAA section 112(f) and concurrently conducting a technology review pursuant to CAA section 112(d)(6). For categories of area sources subject to GACT standards, there is no requirement to address residual risk, but, similar to the major source categories, the technology review is required.

CAA section 112(d)(6) requires the EPA to review standards promulgated under CAA section 112 and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less often than every 8 years. In conducting this review, which we call the ''technology review,'' the EPA is not required to recalculate the MACT floors that were established in earlier rulemakings. *Natural Resources Defense Council (NRDC)* v. *EPA,* 529 F.3d 1077, 1084 (D.C. Cir. 2008). *Association of Battery Recyclers, Inc.* v. *EPA,* 716 F.3d 667 (D.C. Cir. 2013). The EPA may consider cost in deciding whether to revise the standards pursuant to CAA section 112(d)(6). The EPA is required to address regulatory gaps, such as missing standards for listed air toxics known to be emitted from the source category, and any new MACT standards must be established under CAA sections 112(d)(2) and (3), or, in specific circumstances, CAA sections 112(d)(4)

or (h). *Louisiana Environmental Action Network (LEAN)* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020).

B. What are these source categories and how does the current NESHAP regulate their HAP emissions?

The PCE Dry Cleaning NESHAP was originally promulgated September 22, 1993 (58 FR 49376) as 40 CFR part 63, subpart M. Significant amendments were promulgated on June 3, 1996 (61 FR 27788), December 14, 1999 (64 FR 69643), July 27, 2006 (71 FR 42743), and July 11, 2008 (73 FR 39871). The PCE Dry Cleaning NESHAP includes MACT standards which apply to major sources, and GACT standards which apply to area sources of dry cleaning that use the chemical PCE. The PCE Dry Cleaning NESHAP regulates PCE emitted from the dry cleaning process.

Dry cleaning is any cleaning process for clothing and other garments using a solvent other than water. PCE, also known as perc, tetrachloroethene, or tetrachloroethylene has been, historically, the most widely used liquid solvent in dry cleaning. Dry cleaning facilities may provide dry cleaning and laundering services at the location, or the facility may be a drop-off only location that transports the garments to a separate location where the cleaning is performed. Establishments may also offer specialty cleaning services for garments and textiles such as fur, leather, suede, wedding gowns, draperies, and pillows.

PCE dry cleaning machines are classified into two types: Transfer and dry-to-dry. Similar to residential washing machines and dryers, transfer machines include a unit for washing and another unit for drying. Following the wash cycle, PCE-containing articles are manually transferred from the washer to the dryer. The transfer of wet fabrics is the predominant source of PCE emissions in these systems. Transfer machines are prohibited at all existing and new major and area sources due to the NESHAP's requirement that dry cleaning systems eliminate any emissions of PCE while transferring articles between the washer and the dryer or reclaimer. Therefore, transfer machines are no longer sold, and none are known to still be in operation as these machines have reached the end of their useful lives and should have been replaced by dry-to-dry machines. Dry-to-dry machines wash, extract, and dry the articles in a single machine. The articles enter and exit the machine dry. Because the transfer step is eliminated, dry-to-dry machines have much lower emissions than transfer machines.

''Fourth generation'' dry-to-dry machines were introduced in the early 1990s. A fourth generation dry-to-dry machine is a closed-loop system that uses a refrigerated condenser(s) to recycle PCE from the wash cycle, and a carbon adsorption unit(s) to filter PCE from the drum at the end of the dry cycle. The refrigerated condenser is a vapor recovery system into which an air-PCE gas-vapor stream is routed and the PCE is condensed by cooling the gas-vapor stream. The air remaining in the machine at the end of the dry cleaning cycle then passes through a carbon adsorber prior to opening the machine door. The carbon adsorber is a bed of activated carbon into which the air-PCE gas-vapor stream is routed and PCE is adsorbed on the carbon. The use of the carbon adsorber in combination with the refrigerated condenser offers greater emissions reductions over a dry-to-dry machine equipped with only a refrigerated condenser because it reduces the PCE concentration in the air remaining in the machine once the dry cleaning cycle is complete instead of allowing those vapors to be vented or released at the end of the dry cleaning cycle.

The latest generation machines, or ''fifth generation'' machines were introduced in the late 1990s. They have the same control technology as fourth generation machines, but they are also equipped with an inductive fan, internal solvent vapor monitoring devices (sensor), and interlock (lockout) devices that will not allow access to the machine until solvent vapor concentrations are below 300 ppm. The lockout feature ensures that the PCE set-point has been attained before the machine door can be opened, but it does not remove additional PCE.

Per 40 CFR 63.320, a dry cleaning facility is a major source if the facility emits or has the potential to emit more than 10 tons per year of PCE to the atmosphere. A dry cleaning facility is considered an area source if it does not meet the criteria for major sources, as specified in 40 CFR 63.320. However, in lieu of measuring or determining a facility's potential to emit PCE emissions, a dry cleaning facility is a major source if: (1) It includes only dry-to-dry machine(s) and has a total yearly PCE consumption greater than 2,100 gallons as determined according to 40 CFR 63.323(d); or (2) it includes only transfer machine system(s) or both dry-to-dry machine(s) and transfer machine system(s) and has a total yearly PCE consumption greater than 1,800 gallons as determined according to 40 CFR 63.323(d).

As defined by the initial list of source categories publish on July 16, 1992 (57 FR 31576), the PCE Dry Cleaning NESHAP applies to the following major and area sources of HAP emissions:

Major Source Categories

- Commercial Dry Cleaning [Perchloroethylene]—Transfer Machines
- Industrial Dry Cleaning [Perchloroethylene]—Transfer Machines
- Industrial Dry Cleaning [Perchloroethylene]—Dry-to-Dry Machines

Area Source Categories

- Commercial Dry Cleaning [Perchloroethylene]—Transfer Machines
- Commercial Dry Cleaning [Perchloroethylene]—Dry-to-Dry Machines

In general, the PCE Dry Cleaning NESHAP affects three types of dry cleaners that use PCE: Commercial, industrial, and co-residential. Commercial facilities clean household items such as suits, dresses, coats, pants, comforters, curtains, leather clothing, and formal wear. Industrial dry cleaners clean heavily stained articles such as work gloves, uniforms, mechanics' overalls, mops, and shop rags. Co-residential facilities are usually a subset of commercial operations and include dry cleaning operations located in buildings in which people reside. Co-residential facilities are generally found in urban areas where commercial and residential occupancy occur in a single building.

The PCE Dry Cleaning NESHAP identifies all major sources as ''large'' industrial and commercial dry cleaners. These dry cleaners are subject to MACT standards under this NESHAP. It is estimated that there are five or fewer of these major source dry cleaners remaining in the United States.[1] The PCE Dry Cleaning NESHAP requires *new* major source PCE dry cleaners operating dry-to-dry machines to:

- Operate with a refrigerated condenser and carbon adsorber process controls.
- Use an enhanced leak detection and repair (LDAR) program to detect PCE leaks from the machines (*i.e.,* PCE gas analyzer operated according to EPA

[1] Estimated quantity of major source PCE dry cleaners is based on details provided to EPA by state regulators, state small business environmental assistance providers' programs (SBEAP) personnel, and industry trade association representatives. Refer to the docket for this proposed rule (Docket ID No. EPA–HQ–OAR–2005–0155).

Method 21), repair the leaks, and maintain records.

The PCE Dry Cleaning NESHAP requires *existing* major source PCE dry cleaners operating dry-to-dry machines to:

- Operate with a refrigerated condenser or a carbon adsorber as process control.
- Use an enhanced LDAR program to detect PCE leaks from the machines (*i.e.,* PCE gas analyzer operated according to EPA Method 21), repair the leaks, and maintain records.

Dry cleaners that are commonly found in community settings (*e.g.,* shopping centers and strip malls) are typically ''area sources,'' meaning they emit less than 10 tons of PCE each year, and are smaller in size in comparison to major source industrial and commercial PCE dry cleaners. The PCE Dry Cleaning NESHAP standards for these area sources are GACT standards. The PCE Dry Cleaning NESHAP requires *existing* area source PCE dry cleaners operating dry-to-dry machines to:

- Use a halogenated hydrocarbon detector or PCE gas analyzer monthly to detect PCE leaks, repair the leaks, and maintain records.

New area source PCE dry cleaners operating dry-to-dry machines must:

- Operate with a refrigerated condenser and carbon adsorber process controls.
- Use a halogenated hydrocarbon detector or PCE gas analyzer to detect PCE leaks, repair the leaks, and maintain records.

The 2006 amendments to the PCE Dry Cleaning NESHAP eliminated the use of PCE by dry cleaners in co-residential buildings (*e.g.,* a dry cleaner found on the ground floor of an apartment building). EPA recognized that because co-residential dry cleaners are located very close to residences, residents' exposures and their cancer risks could be much higher than for typical area source dry cleaners. As such, the PCE Dry Cleaning NESHAP includes requirements to eliminate risks associated with PCE emissions from co-residential dry cleaners. Under 40 CFR 63.322(o)(5)(i), owners/operators were required to eliminate any PCE emissions from systems located in residential buildings by December 21, 2020. These dry cleaner owner/operators were allowed to replace PCE machines with newer available non-PCE technology. This sunset date allowed owners of existing co-residential sources to operate their machines for their maximum estimated useful life, 15 years, assuming they were first installed no later than December 21, 2005. Additionally, under 40 CFR 63.320(b)(2)(ii) and 63.322(o)(5)(ii), any PCE dry cleaning machines in co-residential buildings that began operating between December 21, 2005 and July 13, 2006, were required to install equipment to aggressively control PCE emissions (*i.e.,* refrigerated condensers, carbon adsorbers, and vapor barriers), and to conduct weekly inspections to detect PCE leaks, repair the leaks, and maintain records, before eliminating PCE emissions by July 27, 2009.

Petitions for judicial review of the 2006 amendments to the NESHAP were filed by the Sierra Club, Halogenated Solvents Industry, Neighborhood Cleaners Association, International Fabricare Institute, and Textile Care Allied Trades Association. *Sierra Club et al.* v. *USEPA,* No. 06–1330 (and consolidated cases) (D.C. Cir.). Petitioners questioned: Whether the EPA reasonably interpreted CAA section 112(d)(6) to allow consideration of risk and costs as factors in determining the extent to which it was necessary to revise standards regulating PCE; whether EPA reasonably determined under section 112(d)(6) that it was necessary to revise standards regulating PCE, and to require elimination of PCE emissions at co-residential systems but not at other systems; whether the EPA had complied with the Regulatory Flexibility Act (RFA); and whether EPA had reasonably denied a petition for reconsideration of the rule submitted by the Sierra Club. Although the case was fully briefed, in 2009 before it could be argued at the D.C. Circuit, the parties agreed to EPA taking a voluntary remand of the rule in order for the then-new administration to consider whether further administrative action was warranted regarding the challenged issues, while leaving the rule in force. As discussed in section III.A of this preamble, we are proposing our response to the voluntary remand as part of this proposal.

C. What data collection activities were conducted to support this action?

For this technology review, the EPA investigated developments in practices, processes, and control technologies through communications and direct discussions with state agencies (including regional, state, and local regulators), Small Business Environmental Assistance Program (SBEAP) personnel, industry stakeholders, and trade association representatives. Details of these conversations are included in the memorandum titled *Technology Review for the PCE Dry Cleaning NESHAP,* December 2021, available in the docket for this action (Docket ID No. EPA–HQ–OAR–2005–0155).

We performed a search of the EPA's Technology Transfer Network (TTN) Clean Air Technology Center—RACT/BACT/LAER Clearinghouse (RBLC) database. The RBLC provides several options for searching the permit database on-line to locate applicable control technologies. We searched the RBLC database for specific dry cleaning process types (''49.002—Dry Cleaning, PERC/Chlorinated Solvents'' and ''49.003—Dry Cleaning, Petroleum Solvents''). In querying results dating back to January 1, 2000, no results were returned when searching for Process Type 49.002 and three results were returned for Process Type 49.003, however none of the information returned was more recent than 2005 or included any new or improved control technologies. In addition to searches conducted using the process type codes above, the RBLC was queried for any sources with ''cleaning'', ''cleaners'', or ''dry cleaning'' in their name. The NAICS and SIC codes for dry cleaners, 812320 and 7216, respectively, were also used to search the RBLC. None of these searches returned relevant information on new or improved control technologies used in dry cleaning facilities. Full details of the RBLC database search in support of this technology review are included in the memorandum titled *Technology Review for the PCE Dry Cleaning NESHAP,* December 2021, available in the docket for this action (Docket ID No. EPA–HQ–OAR–2005–0155).

The EPA also reviewed information and details for facilities that are subject to the PCE Dry Cleaning NESHAP using the Agency's Enforcement and Compliance History Online (ECHO) database. The ECHO database provides integrated compliance and enforcement information for approximately 800,000 regulated facilities nationwide. Using the features in the ECHO database, we searched for dry cleaning facilities by NAICS. The database identified approximately 7,900 facilities. However, these data are not likely to be comprehensive for the dry cleaning source category because not all states submit data on smaller sources to ECHO. Details of the ECHO database search in support of this technology review are included in the memorandum titled *Technology Review for the PCE Dry Cleaning NESHAP,* December 2021, available in the docket for this action (Docket ID No. EPA–HQ–OAR–2005–0155).

D. What other relevant background information and data are available?

To supplement the information collected from the ECHO search, the EPA collected information from the EPA's Office of Resource Conservation and Recovery (ORCR) hazardous waste generator databases. ORCR is responsible for implementation and oversight of the hazardous waste program required by subtitle C of the Resource Conservation and Recovery Act (RCRA). As part of the hazardous waste program, hazardous waste generators must report hazardous waste quantities about a specified threshold, as required by RCRA, subtitle C. Active PCE dry cleaning facilities were identified in the ORCR hazardous waste generator databases, based on a search of reported PCE waste generation, and the NAICS for dry cleaning. Approximately 9,000 active hazardous waste generators were identified in the database. This list does not represent the full list of dry cleaning facilities or indicate the number of facilities subject to the PCE Dry Cleaning NESHAP. For many area sources in this source category the amount of PCE waste generated is below the threshold to notify or report under the RCRA regulations, therefore, there are potentially area source dry cleaning facilities that do not generate enough PCE waste to be included in the hazardous waste generator database. In this technology review, the EPA assumes that the total number of dry cleaning facilities is higher than the approximate 9,000 facilities we were able to identify by the RCRA hazardous waste generator database. A copy of the facility list developed for this technology review can be found in the docket (Docket ID No. EPA–HQ–OAR–2005–0155).

E. How does the EPA perform the technology review?

Our technology review primarily focuses on the identification and evaluation of developments in practices, processes, and control technologies that have occurred since the MACT and GACT standards were promulgated. Where we identify such developments, we analyze their technical feasibility, estimated costs, energy implications, and non-air environmental impacts. We also consider the emission reductions associated with applying each development. This analysis informs our decision of whether it is ''necessary'' to revise the emissions standards. In addition, we consider the appropriateness of applying controls to new sources versus retrofitting existing sources. For this exercise, we consider any of the following to be a ''development'':

- Any add-on control technology or other equipment that was not identified and considered during development of the original MACT and GACT standards;
- Any improvements in add-on control technology or other equipment (that were identified and considered during development of the original MACT and GACT standards) that could result in additional emissions reduction;
- Any work practice or operational procedure that was not identified or considered during development of the original MACT and GACT standards;
- Any process change or pollution prevention alternative that could be broadly applied to the industry and that was not identified or considered during development of the original MACT and GACT standards; and
- Any significant changes in the cost (including cost effectiveness) of applying controls (including controls the EPA considered during the development of the original MACT and GACT standards).

In addition to reviewing the practices, processes, and control technologies that were considered at the time we originally developed (or last updated) the NESHAP, we review a variety of data sources in our investigation of potential practices, processes, or controls to consider. We also review the NESHAP and the available data to determine if there are any unregulated emissions of HAP within the source category, and evaluate this data for use in developing new emission standards. See sections II.C and II.D of this preamble for information on the specific data sources that were reviewed as part of the technology review.

III. Proposed Rule Summary and Rationale

A. What are the results and proposed decisions based on our technology review, and what is the rationale for those decisions?

This section provides a brief discussion of our review of the various information sources listed sections II.C and II.D of this preamble, and our proposed decision pursuant to the CAA section 112(d)(6) technology review to require that all PCE dry-to-dry machines at existing major and area sources have both refrigerated condensers and carbon adsorbers as secondary controls. None of the searches of the RBLC database returned relevant information on new or improved control technologies related to reducing HAP emissions from dry cleaning machines used by facilities in the PCE Dry Cleaning source category. To further identify any developments in practices, processes, and emission control technologies and strategies, the EPA held several meetings with state agencies (including state agency representatives and SBEAP personnel), industry stakeholders and trade association representatives. The EPA asked several questions pertaining to developments since the last technology review on July 26, 2006 (71 FR 42724). The responses to this inquiry did not identify any developments in new or improved control technologies that had not previously been identified and considered that would warrant revision to the existing emission standards for the PCE dry cleaning source category.

Additionally, web search queries for technical literature pertaining to dry cleaning emissions controls, process controls, and work practices did not identify any new or improved practices, processes, or control technologies that were not previously addressed since the technology review performed in 2006.

However, there have been developments in practices, processes, and control technologies that had been identified and considered at the time of adoption of the original NESHAP and/or of the last technology review in 2006. These developments reflect a widespread transition away from some practices that had been allowed to continue for existing sources but were not permitted for new or reconstructed sources. In this technology review, for example, the EPA confirmed with industry representatives that the useful life of a dry-to-dry machine is 15 years. In accordance with the PCE Dry Cleaning NESHAP, PCE dry cleaning machines installed after 1993 for major sources and 2005 for area sources would be equipped with refrigerated condensers and carbon adsorbers. Therefore, the EPA is proposing to require all sources subject to the PCE Dry Cleaning NESHAP, whether new or existing, to be equipped with refrigerated condensers and carbon adsorbers in order to reflect this development.

Refrigerated condensers and carbon adsorbers have been standard secondary controls on all new machines for the last 15 years. The information gathered during the technology review, including details obtained from PCE dry cleaning industry and trade association representatives, revealed that dry-to-dry non-vented dry cleaning machines with refrigerated condensers and carbon adsorbers are the machines that are overwhelmingly used in PCE dry cleaning operations. These fourth

generation and newer machines reuse PCE within the machine, which reduces the PCE emissions from the dry cleaning process. These machines are much more effective at recovering solvent vapors than machines equipped with a carbon adsorber or refrigerated condenser alone.[2]

It has been over 25 years since the initial NESHAP was promulgated in 1993 (58 FR 66287) and 15 years since the last major revisions (71 FR 42724), which required certain machines to be equipped with refrigerated condensers and carbon adsorbers. Even though we expect that almost all currently operating dry cleaning machines have both of these controls, the EPA has determined that we should preclude any possible future use of any machines that do not have both controls. This revision to the standards is necessary to ensure that current improved PCE emissions control achieved by the widespread use of fourth generation (or better) machines is maintained and not compromised by permissible continued operation of earlier generation machines that have exceeded their useful lives. As such, the EPA is proposing to require that all PCE dry-to-dry machines at existing major and area sources have both refrigerated condensers and carbon adsorbers as secondary controls. This revision to the standards will ensure that all dry cleaning systems, both new and existing, will be similarly controlled.

Additionally, the EPA re-examined the use of alternative solvents in use by the dry cleaning industry. This includes the use of non-PCE containing products such as silica-based solvents and high flash point hydrocarbon solvents. As part of this assessment, the EPA reviewed the list of alternative solvents identified in the 2006 PCE Dry Cleaning NESHAP risk and technology review (RTR) (71 FR 42743), and found that, for the purposes of the PCE Dry Cleaning NESHAP MACT or GACT standards, the list of alternative solvents available to the dry cleaning industry remains essentially the same. Since our 2006 assessment, there have been some products that are no longer marketed, and a few products added to the list. In the 2006 PCE Dry Cleaning NESHAP RTR, we looked at the use of alternative solvents as it relates to a potential ban of PCE use. In the 2006 RTR, we identified limitations with the alternative solvents available, when compared to PCE use. These limitations included a comparison of costs, cleaning ability, ease of use, applicability to certain fabrics, safety, and others. After reviewing our assessment made for the 2006 final rule, and the limitations of the alternative solvents available in 2021, we find no new information that would change our 2006 assessment for purposes of the MACT or GACT standards for this industry.

In response to the voluntary remand of the 2006 rule, we are not proposing any amendments addressing the objections raised by the litigants in *Sierra Club et al.* v. *USEPA,* No. 06–1330 and consolidated cases (D.C. Cir.). Since the voluntary remand, EPA has conducted numerous subsequent RTRs for other NESHAPs and source categories and has consistently implemented section 112(d)(6) to take into consideration costs of revising standards and the environmental value of requiring additional HAP reductions when determining whether it is necessary to revise standards taking into consideration developments in practices, processes, and control technologies. We also maintain that we have the discretion to qualitatively consider as a relevant factor the benefits of requiring additional HAP emission reductions and their consequential effect on public health risk under 112(d)(6), as we considered them in the 2006 RTR. Although we are not further considering such reductions and their impacts in this current proposed action because we have not received additional information indicating such are necessary for CAA purposes related to dry cleaning sources beyond the review that we conducted in 2006, we stand by the analyses we conducted and conclusions we reached in the 2006 RTR. Moreover, subsequent reviewing courts have affirmed EPA's now well-established approach of considering costs and cost effectiveness in CAA section 112(d)(6) reviews and making judgments about whether to it is necessary to require additional HAP emissions reductions under CAA section 112(d)(6). *See, e.g., National Association for Surface Finishing* v. *EPA,* 795 F.3d 11–12 (D.C. Cir. 2015) (finding that EPA permissibly considered costs in revising standards under section 112(d)(6)); *see also, Association of Battery Recyclers, et al.* v. *EPA,* 716 F.3d 667, 673–74 (D.C. Cir. 2013) (approving EPA's consideration of cost as a factor in its section 112(d)(6) decision-making and EPA's reliance on cost effectiveness as a factor in its standard-setting). In addressing industry petitioners' challenge to EPA's CAA section 112(d)(6) determinations, the *National Association for Surface Finishing* court explained that ''[r]eductions in emissions are, of course, relevant to the cost effectiveness of emissions-control technologies in controlling emissions.'' *See* 795 F.3d at 12. The court then affirmed that EPA's conclusions ''that more stringent technology-based standards were cost effective and *otherwise* appropriate'' was not arbitrary and capricious. *Id* (emphasis added). The EPA thus maintains that our approach in the 2006 RTR to base our decisions to revise the standards as necessary for dry cleaners located in residential settings, based in part on the unique public health impacts that the additionally mandated HAP reductions would mitigate in that particular context, was warranted under CAA section 112(d)(6).

Consequently, what may have appeared novel in 2006 to the litigants in the earliest stages of the EPA's development of the RTR program (the EPA's consideration of costs and HAP reduction along with the enumerated factors in CAA section 112(d)(6)) has become settled and judicially endorsed practice, and it is not necessary for the EPA to fundamentally re-evaluate that well-established process in this follow-up technology review or in response to the voluntary remand. Moreover, since the 2006 RTR, the EPA has not received any information calling into question the risk-based information that supported our action requiring elimination of PCE emissions from systems located in buildings with a residence. Nor has the EPA received additional information addressing the specific risks presented by PCE emissions to ambient air from co-commercial PCE dry cleaning systems (*e.g.,* those located in strip malls with adjacently located other commercial entities) that suggest that our decision in 2006 to limit the required elimination of PCE emissions to co-residential settings was unwarranted. The EPA requests public comments on our response to the remand, particularly on our proposed determination that no specific revisions to the standards are necessary in light of the remand.

B. What compliance dates are we proposing, and what is the rationale for the proposed compliance dates?

The EPA is proposing that existing affected sources would comply with the proposed amendments in this rulemaking no later than 180 days after

[2] Further details on the evolution of dry cleaning machines and detailed descriptions of the generations of these machines can be found in the refer to the *Technology Review for the Perchloroethylene Dry Cleaning Source Category* memorandum in the docket as well as at the following websites: *https://www.cdc.gov/niosh/docs/hazardcontrol/hc18.html*; *https://www.enviroforensics.com/blog/the-history-of-dry-cleaning-solvents-and-the-evolution-of-the-dry-cleaning-machine/*.

the effective date of the final rule. The affected existing facilities would have to continue to meet the current requirements of 40 CFR part 63, subpart M, until the applicable compliance date of the amended rule. As discussed in section III.B of this preamble, the EPA is proposing to require all dry-to-dry machines at both major and area sources to have both refrigerated condensers and carbon adsorbers as secondary controls. The final action is not expected to be a ''major rule'' as defined by 5 U.S.C. 804(2). Therefore, the effective date of the final rule would be the promulgation date as specified in CAA section 112(d)(10). From our assessment of the timeframe needed for compliance with the entirety of the revised requirements, the EPA considers a period of 180 days to be the most expeditious compliance period practicable. We base this proposed compliance period on several factors. First, from our discussions with state and local agencies, trade association representatives, and other stakeholders, the EPA found that fourth and fifth generation dry-to-dry machines are standard throughout the industry. Additionally, the EPA confirmed that the useful life of a dry-to-dry machine is 15 years, and that new dry cleaning machines sold in the last 20 years are only fourth and fifth generation machines. Based on these findings, we believe that almost all of the industry is already in compliance with the proposed amendments. The 180 days is provided as a courtesy to allow familiarity with the proposed changes. We solicit comment on this proposed compliance period, and we specifically request submission of information from the sources in the major and area source categories regarding specific actions that would need to be undertaken to comply with the proposed amended requirements and the time needed to make the adjustments for compliance with any of the revised requirements. We note that information provided may result in changes to the proposed compliance date.

IV. Summary of Cost, Environmental, and Economic Impacts

A. What are the affected sources?

The PCE Dry Cleaning NESHAP prescribes a combination of equipment, work practices, and operational requirements. The NESHAP allows regulated sources to determine their major or area source status based on the annual PCE purchases for all machines at a facility. The consumption criterion (which affects the amount of PCE purchased) varies depending on multiple variables, including number of machines, size of business, etc. The affected source is each individual dry cleaning system that uses PCE. Consequently, a single dry cleaning facility could comprise multiple affected sources, if it has multiple dry cleaning systems onsite. As a result, some of a facility's systems could be subject to ''new'' source requirements under the NESHAP, and some could be ''existing'' sources, depending upon when they were placed into service.

The July 27, 2006, final rule amendments (71 FR 42743) indicate that at that time, there were approximately 34,000 dry cleaning facilities in the United States, approximately 28,000 of which used PCE. Those estimated counts of the number of overall dry cleaners and PCE dry cleaners are prior to business impacts from the 2008 financial crisis, the coronavirus (COVID–19) pandemic of 2020–2021, recent shifts in consumer demands, changes in garment technologies, fashion trends, dry cleaning machine conversions to alternative solvents, and other factors that have resulted in reductions in the number of PCE dry cleaning operations. Based on information provided by dry cleaning industry stakeholders, including trade organizations, the EPA estimates that the number of PCE dry cleaners decreased by 20 to 30 percent due to the 2008 financial crisis, the aforementioned demand trends in the industry, and increasing replacements of PCE operations with alternative solvent technologies. Additionally, the EPA estimates that another 10 to 15 percent of PCE dry cleaners have ceased operation due to financial impacts from the COVID–19 pandemic. As such, the EPA estimates that there are approximately 10,000 to 15,000 PCE dry cleaning facilities in the U.S.

B. What are the air quality impacts?

The EPA is proposing that all PCE dry-to-dry machines operate with both refrigerated condensers and carbon adsorbers as secondary controls (*i.e.,* be fourth or fifth generation machines). The PCE dry cleaning facilities that are in operation have most likely realized the reduction in emissions associated with operating both refrigerated condensers and carbon adsorbers. Additionally, any new machines have been required to have both refrigerated condensers and carbon adsorbers since the original promulgation of part 63, subpart M, in 1993 (for major sources) and the 2006 RTR (for area sources); any existing third generation or older machines at the time of those rules are now beyond their 15-year expected lifespan. For those facilities who may still be operating older machines, the proposed amendments of this rulemaking would reduce emissions by mandating the use of newer machines with the required controls.

Indirect or secondary air emissions impacts are impacts that would result from the increased electricity usage associated with the operation of control devices (*i.e.,* increased secondary emissions of criteria pollutants from power plants). Energy impacts consist of the electricity and steam needed to operate control devices and other equipment that would be required under this proposed rule. The EPA expects minimal secondary air emissions impacts or energy impacts from this rulemaking.

C. What are the cost impacts?

Any new PCE dry-to-dry machines purchased in the last 20 years for this source category are closed-loop dry-to-dry machines with a refrigerated condenser and a carbon adsorber [3] and thus would not be impacted by these proposed amendments. The PCE dry cleaning operations that would be impacted by the proposed amendments would most likely already have incurred the costs of installing and operating these fourth-generation machines. Specifically, any older machines (*i.e.,* third generation or prior transfer machines or dry-to-dry machines without refrigerated condenser and a carbon adsorber) would now be beyond their projected useful life, and we expect that operators would have already replaced these machines with fourth- and fifth-generation machines, as part of continued PCE dry cleaning operations. However, we also recognize that there may be some facilities that are still operating older PCE machines. We expect that if there are any facilities operating older machines, they would be area sources. For reasons previously discussed in section II.C and II.D of this preamble, the number of older machines in use is unknown. The EPA is soliciting comment on the number of sources operating older machines and will reassess the cost and economic impacts if we receive additional data.

Based on available information, the EPA concludes that most or all existing PCE dry cleaning facilities that are subject to the NESHAP would be able to comply with the proposed requirements without incurring additional capital or operational costs because they have

[3] U.S. EPA, Office of Air Quality Planning and Standards. Phone Conference Communication with *Dry Cleaning & Laundry Institute (DLI)* and *National Cleaners Association (NCA)* representatives. March 2021.

purchased newer machines as part of normal business operations. There may be small number of facilities operating older machines, but we do not have information on these facilities to determine the full cost impacts to these entities. We have assessed the costs associated with reading and understanding the proposed amendments as a total one-time cost of $108 per facility, using a labor rate for 4 hours of review time, as described in section IV. D of this preamble. Based on an estimate of 10,000 to 15,000 facilities that are subject to the PCE Dry Cleaning NESHAP, the total cost is estimated to be in a range of $1,080,000 to $1,620,000 nationwide.

D. What are the economic impacts?

Economic impact analyses focus on changes in market prices and output levels. If changes in market prices and output, such as clothes to be cleaned in the primary markets served by dry cleaners, are significant enough, impacts on other markets may also be examined. Both the magnitude of costs needed to comply with a proposed rule and the distribution of these costs among affected facilities can have a role in determining how the market would change in response to a proposed rule. To estimate the economic impacts of this proposal, the EPA reviewed the mean hourly wage of $12.29 per hour indicated by the Bureau of Labor Statistics for laundry and dry cleaning workers in 2021. We then applied a benefits and overhead factor of 1.1 to calculate a total compensation rate of $26.86 per hour. Additionally, we estimated 4 hours for a dry cleaning worker to familiarize themselves with the proposed amendments to the rule, and calculated a cost of $108 per facility ($23.86/hr × 4 hr/facility = $107.44, or $108/facility). This is a conservative estimate. We anticipate that some facilities may not require 4 hours to review the proposed amendments to the rule. These costs are not expected to result in a significant impact to primary markets served by dry cleaners.

We do not anticipate any significant economic impacts from these proposed amendments to require all dry-to-dry machines to have both refrigerated condensers and carbon adsorbers as secondary controls. This is consistent with our assumptions made in the original rule development that the useful life of a machine is 15 years. Machines installed after 1993 for major sources and 2005 for area sources are to be equipped with refrigerated condensers and carbon adsorbers, in accordance with the NESHAP. Thus, given the useful life of a typical dry-cleaning machine, the EPA expects that most or all sources in the regulated source categories would have discontinued use of third generation or older machines by 2021.

E. What are the benefits?

Although the EPA does not anticipate reductions in HAP emissions as a result of the proposed amendments, the Agency believes that the action, if finalized as proposed, would result in improved clarity to the rule. Specifically, the proposed amendments would revise the standards such that it is clear that only fourth (or newer) generation machines can be used in PCE solvent dry cleaning operations. This requirement is implied in the useful life determination at the inception of the original NESHAP; however, this proposed amendment would make this assumption clear and would work to eliminate any older machines (third generation and prior) that could still be operating. This action would further protect public health and the environment and would ultimately result in less potential confusion or misinterpretation by the regulated community.

F. What analysis of environmental justice did we conduct?

Executive Order 12898 directs the EPA, to the greatest extent practicable and permitted by law, to make environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies and activities on minority populations and low-income populations in the United States. (59 FR 7629, February 16, 1994.) Additionally, Executive Order 13985 was signed to advance racial equity and support underserved communities through Federal Government actions (86 FR 7009, January 20, 2021). 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'' (*https://www.epa.gov/environmentaljustice*). In recognizing that minority and low-income populations often bear an unequal burden of environmental harms and risks, the EPA continues to consider ways of protecting them from adverse public health and environmental effects of air pollution. To examine the potential for any EJ issues that might be associated with the source categories, we performed a demographic analysis, which is an assessment of individual demographic groups of the populations living within 5 kilometers (km) and within 50 km of the facilities. The EPA then compared the data from this analysis to the national average for the demographic indicators.

In the analysis, we evaluated the percentage of minority and low-income groups within the populations that live near identified PCE dry cleaning facilities. The PCE Dry Cleaning NESHAP applies to sources often operating as small facilities, and limited location data for these small subject facilities were available, adding considerable uncertainty to the analysis. As described in the technology review memorandum, available in the docket for this action, and section II.C of this preamble, we did conduct searches for available information. The demographic results do not account for emission or risk impacts from sources and may not be fully representative of the full distribution of facilities across all locations and populations. This analysis provides an indication of the potential for disparities in human health or environmental effects.

Our analysis includes the general population of dry cleaners across the country and does not differentiate which facilities are PCE major and area source dry cleaners. As stated above, our analysis indicates that sources are likely to operate compliant technologies to meet the proposed standard. Based upon the number of facilities in this analysis (9,080 facilities), we find that approximately 48 percent of the U.S. population lives within 5 km of a facility, and approximately 87 percent live within 50 km of a facility. We find that dry cleaner facilities are generally located in areas where within the 5 km distance the category of minority demographics are higher than the national average, but demographics generally match the national average within 50 km. We also note that demographics analyses for individual urban facilities often show that the percentages of various minority and disadvantaged populations tend to exceed the national averages due to the urban locations. The results of the demographic analysis for populations within 5 km of the facilities within the

source category indicate that the percentage of the minority population (the total population minus the white population) is higher when compared to the national percentage of people who are minority (an average of 48 percent versus 40 percent). These comparisons also hold true for other demographic groups (African American, Other and Multiracial Groups, and Hispanics), whose populations near dry cleaning facilities are approximately an average of 3 percent greater the national average. The demographic group composed of people living in linguistic isolation was an average of approximately 1 percent greater than the national average. The percentages of people in all the remaining demographic groups were below the national average for their respective demographic. The methodology and the results of the demographic analysis are presented in a technical report, *Technology Review—Analysis of Demographic Factors for Populations Living Near the Dry-cleaners for Major and Area Sources,* available in this docket for this action (Docket ID EPA–HQ–OAR–2005–0155).

TABLE 1—PROXIMITY DEMOGRAPHIC ASSESSMENT RESULTS

	Nationwide	Source category	
		Population within 50 km of 9,080 facilities	Population within 5 km of 9,080 facilities
Total Population	328,016,242	285,838,206	156,313,800
White and Minority by Percent			
White	60	60	52
Minority	40	40	48
Minority by Percent			
African American	12	13	15
Native American	0.7	0.5	0.4
Hispanic or Latino (includes white and nonwhite)	19	18	22
Other and Multiracial	8	8	11
Income by Percent			
Below Poverty Level	13	13	14
Above Poverty Level	87	87	86
Education by Percent			
Over 25 and without a High School Diploma	12	12	12
Over 25 and with a High School Diploma	88	88	88
Linguistically Isolated by Percent			
Linguistically Isolated	5	5	7

Notes:
• The population numbers and demographic percentages are based on the Census' 2015–2019 American Community Survey five-year averages and include Puerto Rico. Demographic percentages based on different averages may differ.
• Minority population is the total population minus the white population.
• To avoid double counting, the ''Hispanic or Latino'' category is treated as a distinct demographic category for these analyses. A person is identified as one of five racial/ethnic categories above: White, African American, Native American, Other and Multiracial, or Hispanic/Latino. A person who identifies as Hispanic or Latino is counted as Hispanic/Latino for this analysis, regardless of what race this person may have also identified as in the Census.

This action is not likely to change levels of emissions near facilities. Based on our technology review, we did not identify, and are not requiring, any new add-on control technologies, process equipment, work practices or procedures that were not already in place when the NESHAP was promulgated in 1993 or considered when the NESHAP was last reviewed in 2006; and we did not identify other developments in practices, processes, or control technologies that would result in additional emission reductions for purposes of these MACT and GACT standards, beyond the transition to greater use of fourth and fifth generation machines. Given the useful life of a dry cleaning machine, and the fact that industry should already be operating the newer machines with both refrigerated condensers and carbon adsorbers as secondary controls, we do not anticipate reductions in HAP emissions as a result of the proposed amendments.

V. Request for Comments

We solicit comments on this proposed action. In addition to general comments on this proposed action, we are also interested in additional data that may improve the analyses. We are specifically interested in receiving any information regarding the number of third generation and earlier model dry cleaning machines that potentially could still be operating, and on other developments in practices, processes, and control technologies that reduce HAP emissions beyond the widespread shift to fourth generation (or better) machines.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was, therefore, not submitted to OMB for review.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. The action does not contain any information collection activities.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are industrial and commercial dry cleaning facilities that use PCE. The North American Industry Classification System (NAICS) codes applicable to 40 CFR part 63, subpart M, are 812310 (coin-operated laundries and dry cleaners), 812320 (dry cleaning and laundry services other than coin-operated services), and 812332 (industrial launderers). The small business size definitions for those industries are $8.0 million, $6.0 million, and $41.5 million respectively. The costs associated with reading and understanding the proposed amendments are a one-time cost of $108 per facility and are not significant. In addition, the useful life of a PCE dry-to-dry machine is assumed to be 15 years, and the industry has already purchased fourth or fifth generation dry-to-dry machines that are in compliance with these amendments as part of normal operational costs. We have therefore concluded that this action will not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector. This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. While this action creates an enforceable duty on the private sector, the cost does not exceed $100 million or more.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not 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. The action affects private industry and does not impose economic costs on state or local governments.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action has tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. The EPA consulted with tribal officials under the EPA Policy on Consultation and Coordination with Indian tribes early in the process of developing this regulation to permit them to have meaningful and timely input into its development. A summary of that consultation is provided in the docket for this action (Docket ID No. EPA–HQ–OAR–2005–0155).

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

The documentation for this decision is contained in section IV.B of this preamble and the technical report, *Risk and Technology Review Analysis of Demographic Factors for Populations Living Perchloroethylene Dry Cleaning Facility Source Category Operations.*

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Michael S. Regan,

Administrator.

For the reasons stated in the preamble, EPA proposes to amend 40 CFR part 63 as set forth below:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart M—National Perchloroethylene Air Emission Standards for Dry Cleaning Facilities

■ 2. Section 63.322 is amended by:
■ a. Revising paragraph (a) introductory text;
■ b. Adding paragraph (a)(4); and
■ c. Revising paragraph (o)(2).

The revisions and addition read as follows:

§ 63.322 Standards.

(a) Before [date 180 days after date of publication of the final rule in the **Federal Register**], the owner or operator of each existing dry cleaning system and of each new transfer machine system and its ancillary equipment installed between December 9, 1991, and September 22, 1993, shall comply with either paragraph (a)(1) or (2) of this section and shall comply with paragraph (a)(3) of this section if applicable. On and after [date 180 days after date of publication of the final rule in the **Federal Register**], the owner or operator of any existing dry cleaning system shall comply with paragraph (a)(4) of this section.

* * * * *

(4) The owner or operator of each existing dry cleaning system shall route the air-perchloroethylene (PCE) gas-vapor stream contained within each dry cleaning machine through a refrigerated condenser and pass the air-PCE gas-vapor stream from inside the dry cleaning machine drum through a non-vented carbon adsorber or equivalent control device immediately before the door of the dry cleaning machine is opened. The carbon adsorber must be

desorbed in accordance with manufacturer's instructions.

* * * * *

(o) * * *

(2) The owner or operator of each dry cleaning system at an area source shall route the air-PCE gas-vapor stream contained within each dry cleaning machine through a refrigerated condenser and pass the air-PCE gas-vapor stream from inside the dry cleaning machine drum through a non-vented carbon adsorber or equivalent control device immediately before the door of the dry cleaning machine is opened. The carbon adsorber must be desorbed in accordance with manufacturer's instructions.

* * * * *

■ 3. Section 63.324 is amended by revising paragraphs (d)(5) and (6) to read as follows:

§ 63.324 Reporting and recordkeeping requirements.

* * * * *

(d) * * *

(5) The date and monitoring results (temperature sensor or pressure gauge), as specified in § 63.323, when a refrigerated condenser is used to comply with § 63.322(a), (b), or (o); and

(6) The date and monitoring results, as specified in § 63.323, when a carbon adsorber is used to comply with § 63.322(a)(2) or (b)(3).

* * * * *

■ 4. Section 63.325 is amended by revising paragraph (a)(7) to read as follows:

§ 63.325 Determination of equivalent emission control technology.

(a) * * *

(7) Information on the cross-media impacts (to water and solid waste) of the candidate emission control technology and demonstration that the cross-media impacts are less than or equal to the cross-media impacts of a refrigerated condenser and carbon adsorber.

* * * * *

[FR Doc. 2021–26469 Filed 12–23–21; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

48 CFR Part 552

[GSAR Case 2021–G522; Docket No. GSA–GSAR–2021–0028; Sequence No. 1]

RIN 3090–AK39

General Services Administration Acquisition Regulation; Contract Requirements for High-Security Leased Space

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Proposed rule.

SUMMARY: GSA is proposing to amend the General Services Administration Acquisition Regulation (GSAR) to implement Section 4 requirements of the Secure Federal Leases from Espionage and Suspicious Entanglements Act (the Act or Secure Federal LEASEs Act). The Act addresses the risks of foreign ownership of Government-leased real estate and requires the disclosure of ownership information for high-security space leased to accommodate a federal agency.

DATES: Interested parties should submit written comments to the Regulatory Secretariat Division at the address shown below on or before February 25, 2022 to be considered in the formation of the final rule.

ADDRESSES: Submit comments in response to GSAR Case 2021–G522 to the Federal eRulemaking portal at *https://www.regulations.gov* by searching for ''GSAR Case 2021–G522''. Select the link ''Comment Now'' that corresponds with ''GSAR Case 2021–G522''. Follow the instructions provided at the ''Comment Now'' screen. Please include your name, company name (if any), and ''GSAR Case 2021–G522'' on your attached document. If your comment cannot be submitted using *https://www.regulations.gov,* call or email the points of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Please submit comments only and cite ''GSAR Case 2021–G522'' in all correspondence related to this case. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *https://www.regulations.gov,* approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Carroll, Procurement Analyst, at 817–253–7858 or *GSARPolicy@gsa.gov,* for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.* Please cite GSAR Case 2021–G522.

SUPPLEMENTARY INFORMATION:

I. Background

On Dec. 31, 2020, the then president signed into law the Secure Federal Leases from Espionage and Suspicious Entanglements Act (Secure Federal LEASEs Act), (Pub. L. 116–276, 134 Stat. 3362). The Act imposes disclosure requirements regarding the foreign ownership, particularly ''beneficial ownership,'' of prospective lessors of ''high-security leased space'' (*i.e.,* property leased to the Federal government having a security level of III or higher).

These requirements of the statute are applicable to leases by the U.S. General Services Administration (GSA), the Architect of the Capitol, ''or the head of any Federal agency, other than the Department of Defense (DOD), that has independent statutory leasing authority'' (Federal lessees). The Act is not applicable to DOD or to the intelligence community. In that regard, Section 2876 of the fiscal year (FY) 2018 National Defense Authorization Act (NDAA) (Pub. L. 115–91) already provides DOD similar authority to obtain ownership information with respect to its high-security leased space.

GSA implemented a regulatory action for Sections 3 and 5 of the Act, effective June 30, 2021, as an interim rule (GSAR 2021–G527,[1] 86 FR 34966). The interim rule applies to GSA and to agencies relying upon GSA's leasing authority. This proposed rule addresses GSA's implementation of Section 4 of the Act.

The Act addresses national security risks identified in the Government Accountability Office (GAO) report, GSA Should Inform Tenant Agencies When Leasing High-Security Space from Foreign Owners, dated January 2017 (GAO–17–195). This report found certain high-security Federal agencies were in buildings owned or controlled by foreign entities. According to the report, most Federal tenants were unaware the spaces GAO identified were subject to foreign ownership or control, exposing these agencies to the heightened risk of surreptitious physical or cyber espionage by foreign actors. The report also noted GAO could not identify the owners of approximately one-third of the Federal government's high-security leases because such

[1] GSAR 2021–G527, **Federal Register** Document.

ownership information was unavailable for those buildings.

As the U.S. Government's ''landlord,'' GSA serves as the central leasing agent for Federal leases and is responsible for managing and obtaining space on behalf of multiple Federal agencies. When GSA enters into a leasing agreement, the agency becomes the ''tenant'' of GSA, with GSA acting as the lessee of the property.

Prior to the interim rule, GSAR 2021–G527, GSA used information contained in the System for Award Management (SAM) to collect foreign ownership information for potential lessors, including immediate or highest-level owners. However, as Congress recognized in the Act, SAM does not capture more nuanced forms of foreign control such as entities involved in financing properties or beneficial ownership. Following the implementation of the interim rule, for GSA and agencies relying upon GSA's leasing authority, foreign ownership information for potential lessors, including immediate or highest-level owners, is collected manually (paper copy) through the GSAR representation clause 552.270–33 (Foreign Ownership and Financing Representation for High-Security Leased Space). This proposed rule will expand that clause to address the representation clause to address beneficial ownership.

GSA is currently reviewing and investigating potential future implementation steps and potential updates through electronic means to implement the requirements of the Act, including externally (*e.g.,* System for Award Management) or internally (*e.g.,* GSA's Lease Offer Platform). As these alternatives are not yet available, this proposed rule will require reporting on an action-by-action basis.

What is ''High-Security Leased Space''?

The statute defines ''high security leased space'' as ''space leased by a Federal lessee that—(A) will be occupied by Federal employees for nonmilitary activities; and (B) has a facility security level of III, IV or V, as determined by the Federal tenant in consultation with the Interagency Security Committee, the Department of Homeland Security, and the General Services Administration.'' Facility security levels and the process for determining these are outlined in the Interagency Security Committees publication ''The Risk Management Process.'' [2]

[2] Interagency Security Committees publication ''*The Risk Management Process*'', March 2021.

New Disclosure Requirements

Section 4 of the Act, specifically addressed in this proposed rule, imposes disclosure requirements for beneficial ownership:

- Subject to the development of GSA's government-wide plan for obtaining ownership information outlined in Section 4 of the Act, covered entities will be required to disclose information about beneficial ownership.

What is a ''Beneficial Owner''?

Unlike the direct control–based immediate owner and highest-level owner, the Act defines the term ''beneficial owner'' as meaning ''with respect to a covered entity, each natural person who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise—(i) exercises control over the covered entity; or (ii) has a substantial interest in or receives substantial economic benefits from the assets of the covered entity.'' However, a beneficial owner of a covered entity does not include: A minor child, a person acting as a nominee, intermediary, custodian, or agent on behalf of another person; a person acting solely as an employee of the covered entity and whose control over or economic benefits from the covered entity derives solely from the employment status of the person; a person whose only interest in the covered entity is through a right of inheritance or a creditor of the covered entity unless either also meets the definition of ''beneficial owner.''

The Act is one of several recent examples of congressional concern about foreign ownership and control and congressional action in the world of government contracting to help address potential national security concerns. *See, e.g.,* FY 2021 NDAA (Pub. L. 116–283), section 819, Modifications to Mitigating Risks Related to Foreign Ownership, Control, or Influence of DOD Contractors and Subcontractors; section 885, Disclosure of Beneficial Owners in Database for Federal Agency Contract and Grant Officers; section 6403, Beneficial Ownership Information Reporting Requirements, and, as of June 30, 2021, GSAR 2021–G527, Immediate and Highest-Level Owner for High-Security Leased Space.

Because of the related rulemaking, there are several definitions of ''beneficial owner'' (or ''beneficial ownership'').

The United States Securities and Exchange Commission (SEC) Definition

Section 885 (Disclosure of beneficial owners in database for Federal agency contract and grant officers) of the FY 2021 NDAA (Pub. L. 116–283) [3] states that beneficial ownership has the meaning given under section 847 (Mitigating risks related to foreign ownership, control, or influence of Department of Defense contractors or subcontractors) of the FY 2020 NDAA (Pub. L. 116–92).[4] Section 847 does not specifically define beneficial ownership but requires ''beneficial ownership'' to ''be determined in a manner that is not less stringent than the manner set forth in section 240.13d–3 of title 17, Code of Federal Regulations.'' This Code of Federal Regulations reference is the SEC definition.[5] The SEC definition mainly concerns the beneficial owner of a security (*e.g.,* stock/bond/option for a corporation), not the corporation or company-at-large.

Corporate Transparency Act Definition

The Corporate Transparency Act (CTA) definition can be found at section 6403 of the FY 2021 NDAA. This section defines ''beneficial ownership'' as, with respect to an entity, an individual who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise (i) exercises substantial control over the entity; or (ii) owns or controls not less than 25 percent of the ownership interests of the entity.

Secure Federal LEASEs Act Definition

A ''beneficial owner'' is with respect to a covered entity, each natural person who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise—(i) exercises control over the covered entity; or (ii) has a substantial interest in or receives substantial economic benefits from the assets of the covered entity.

GSA's Interpretation

GSA interprets that the SEC definition is too limiting for use in the representation clause because it's concerned with the beneficial owner of a security rather than a company or corporation. The Secure Federal LEASEs Act and the CTA definitions are similar. Both definitions similarly characterize a beneficial owner as someone who (i) controls a covered entity, or (ii) has a substantial interest. The primary difference between the two is related to ''substantial interest.'' The Secure Federal LEASEs Act states that a beneficial owner is someone who ''. . . has a substantial interest in or receives substantial economic benefits from the

[3] FY 2021 NDAA.

[4] FY 2020 NDAA.

[5] 17 CFR 240.13d–3.

assets of the covered entity'' while the CTA definition says a beneficial owner ''owns or controls not less than 25 percent of the ownership interests of the entity.'' GSA interprets that the CTA definition meets the intent of the SFLA definition. As such, GSA intends to use the CTA definition (and therefore incorporates it into the GSAR representation clause at 552.270–33) because it's more specific (''not less than 25 percent'' as opposed to having to define ''substantial interest'' or ''substantial economic benefits'') and because it would allow GSA to leverage Treasury's Financial Crimes Enforcement Network's (FinCEN) efforts to collect beneficial owner information for all corporations. GSA does not believe this definition to be ''not less stringent'' than the SEC definition.

Covered entities already provide certain information on immediate and highest-level ownership, per Office of Management and Budget (OMB) Control Numbers 9000–0097, 9000–0185, and 3090–0324. However, covered entities will need to provide additional disclosure of creditors who may be deemed beneficial owners if they either exercise substantial control over the covered entity or owns or controls not less than 25 percent of the ownership interests of the covered entity. Therefore, property owners will need to take this provision into account when considering financing options for leasing high-security space to the Federal Government.

Government-Wide Plan for Obtaining Ownership Information

Section 4 of the Act requires GSA, in conjunction with the Office of Management and Budget (OMB), to develop a Government-wide plan for agencies to identify all immediate, highest-level, or beneficial owners of high-security leased spaces before entering into a lease agreement with a covered entity for the accommodation of a Federal tenant in a high-security leased space.

The plan must require the disclosure of any immediate, highest-level, or beneficial owner that is a foreign person and notification by the Federal lessee of high-security space to the affected Federal tenant of such foreign ownership. The plan, however, must exclude collecting ownership information on widely held pooled-investment vehicles, mutual funds, trusts, or other pooled-investment vehicles. The Act requires GSA to submit the plan to specific Congressional committees by Dec. 31, 2021, and to implement the plan by Dec. 31, 2022. By Dec. 31, 2023, GSA will submit a report to the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Transportation and Infrastructure of the House of Representatives on the status of the implementation of the plan, including the number of disclosures made. This plan is addressed separately, including in Federal Management Regulation (FMR) 2021–102–1.

II. Requirements Contained in This Rulemaking and Related Rulemakings

With this document, GSA is proposing to implement Section 4 of the Act. GSA previously implemented Section 3 and Section 5 of the Act through separate rulemaking at GSAR 2021–G527 (86 FR 34966) on June 30, 2021.

Section 4 of the Act requires the identification of beneficial owners of high-security leased spaces and will be addressed through this GSAR Case 2021–G522 and FMR Case 2021–102–1. In addition, the Federal Acquisition Regulatory (FAR) Council has opened FAR Case 2021–005 which will implement sections 885 and 6403 of the NDAA for FY 2021 (Pub. L. 116–283) to require certain offerors to disclose beneficial ownership information in their offers for contracts over the simplified acquisition threshold.

Section 3 (already implemented through separate rulemaking that also included Section 5)—

- Requires Federal lessees for high-security leased space to require covered entities to identify and disclose whether the owner of the leased space, including an entity involved in the financing thereof, is a foreign person or a foreign entity, including the country associated with the ownership entity, before entering into a lease agreement. Covered entities must provide Federal lessees such information—
  - ○ when first submitting proposals in response to a solicitation for offers issued by the lessee; and
  - ○ annually, to include the list of immediate or highest-level owners of the covered entity during the preceding one-year period of occupancy.
- Requires the Federal lessee to notify the Federal tenant in writing if such a disclosure of foreign ownership is made and consult with the tenant regarding any security concerns prior to awarding a new lease agreement.

Section 5 (already implemented through separate rulemaking that also included Section 3)—

- Requires that leases for high-security space include certain language regarding access to the high-security leased space by the covered entity and any member of the property management company.

As noted in GSAR Case 2021–G527, other agencies may need to do additional rulemaking, related to Sections 3 and 5, because the GSAR only governs the contract terms and conditions for leased space procured by GSA and its delegated agencies. Section 4 is similar in that regard. This proposed rule, and the GSAR, only governs the contract terms and conditions for leased space procured by GSA and its delegated agencies. Other agencies may need to do additional rulemaking. Additionally, a separate Federal Management Regulation rule (2021–102–1) will be applicable to leases by the Architect of the Capitol, ''or the head of any Federal agency, other than the Department of Defense (DOD), that has independent statutory leasing authority'' (Federal lessees).

III. Authority for This Rulemaking

Title 40 of the United States Code (U.S.C.) Section 121 authorizes GSA to issue regulations, including in the GSAR, to control the relationship between GSA and contractors. In addition, the Secure Federal LEASEs Act, authorizes GSA, in consultation with OMB, to issue a Government wide plan for Federal agencies with independent lease authority to collect foreign ownership information for high-security leased space. The Government-wide plan will be addressed separately, including in the Federal Management Regulation 2021–102–1.

IV. Revised GSAR Requirements

With this rule, GSA is proposing to revise one GSAR representation clause. The revised representation is 552.270–33 (Foreign Ownership and Financing Representation for High-Security Leased Space). This representation clause applies to new lease awards, the exercise of options for current leases, lease extensions, and ownership changes for high-security leased space. Except where otherwise provided, the Act's disclosure requirements, shall apply with respect to any lease or novation agreement entered into on or after December 31, 2022, involving high-security leased space. That includes new, renewal, succeeding, expansion, superseding, extension, and replacing leases and novations. The disclosure requirements specific to Section 3 already apply as of June 30, 2021.

The revised GSAR representation implemented at 552.270–33 now adds the requirement that offerors for high-security leased space identify whether the offeror does or does not have a beneficial owner(s), and if so, if the

beneficial owner(s) is a foreign person(s). Where there is an affirmative disclosure of any immediate, highest-level, or beneficial owner that is a foreign person, the offeror or lessor must represent the name, current residential or business street address, and an identifying number or document that verifies identity as a United States person, foreign person, or foreign identity of each beneficial owner. This representation also applies upon extensions, exercise of renewal options and change of ownership/novations.

The disclosures required by Section 3 for immediate and highest-level owner are already captured by GSAR clause 552.270–33 implemented by GSAR Case 2021–G527 (86 FR 34966).

V. Expected Impact of the Rule

GSA anticipates that this rule will have an impact on current Federal lessors of high-security leased space, future potential lessors of high-security leased space, and the Federal lessor industry of high-security leased space. The rule seeks to ensure effective implementation and enforcement of the national security measures imposed by the Secure Federal LEASEs Act with minimal disruption to the mission of GSA and its Federal tenants and Federal lessors. As set forth in Section VI.(d) below, GSA recognizes the benefits that will result from this rule.

GSA notes that this rule is one of several actions with regard to the Secure Federal LEASEs Act and other statutes regarding foreign ownership by GSA, other agencies with lease authority promulgating their own rules, and by the FAR Council. GSA understands that the impact of actions dealing with foreign ownership, including specifically beneficial owners, is not well understood and is still being assessed.

In addition, GSA is seeking public comment, including, as indicated below, on the potential impact of this rule on Federal lessors. After considering the comments received, a final rule will be issued, taking into account and addressing the public comments. GSA plans to share public comments received on such questions with other agencies and the FAR Council.

VI. Regulatory Impact Analysis

The cost and benefit impacts of amending the General Services Administration Acquisition Regulation (GSAR) to implement the Section 4 requirements outlined in the Secure Federal LEASEs Act (SFLA) (Pub. L. 116–276) are discussed in the analysis below. This analysis was developed by GSA in consultation with agency procurement officials and the GSA Office of Leasing. Section VI.(h) of this rule is requesting specific feedback regarding the impact of this rule, as well as other pertinent policy questions of interest, in order to inform finalization of this and potential future subsequent rulemakings.

(a) Risks to Industry of Not Complying With SFLA

As a strictly contractual matter, an organization's failure to submit an accurate representation to the Government constitutes a breach of contract that can lead to cancellation, termination, and financial consequences. Therefore, it is important for contractors to develop a compliance plan that will allow them to submit accurate representations to the Government in the course of their offers.

GSA notes that this rule does not authorize GSA lease contracting officers to use the information disclosed by offerors as a differentiating factor for selection of a lease award, nor does it authorize GSA to terminate a lease, prevent a novation, or otherwise decline to make an award based on the disclosure. As such, GSA estimates that this rule will not result in these activities, and therefore no moving costs have been included in this regulatory impact analysis.

(b) Contractor Actions Needed for Compliance

GSA assumes that most Federal lessors maintaining high-security leased space or Federal lessors that are competing for solicitations for high-security leased space are already familiar with the majority of the requirements of this rule, or, similarly, will not find the requirements of this interim rule as anything significantly more than what is currently expected. GSA previously implemented ownership disclosures requirements through internal policy,[6] GSA's Request for Lease Proposals (or solicitations), and GSA's guidance through its public-facing Leasing Desk Guide[7] and Leasing Alerts and Lease Acquisition Circulars.[8]

(1) GSA Leasing—Current Processes

Regardless of who owns the leased space, Federal agencies are already taking risk management measures appropriate for the security level of the space. The GSA Leasing Desk Guide[9] outlines requirements and standards for new and replacement space. In Chapter 19 (issued in 2012), it provides instructions for competitive procurements based on the Interagency Security Committee (ISC),[10] Physical Security Standards, and it outlines the Public Buildings Service's (PBS) responsibilities for performing background investigations on the lessors' contractors. Additionally, GSA Leasing Alert LA–21–10,[11] issued on August 11, 2021, revised GSA's security documents for leased space to align with the ISC's updated (2019) countermeasures.

In addition, a 2018 GSA Leasing Alert,[12] provided required and recommended countermeasures for lessors related to cybersecurity protections and precautions in leased facilities. It establishes lease language that prohibits lessors from connecting any portion of their building and access control systems (BACS) to any federally-owned or operated IT network and requires notification for cybersecurity incidents that impact a federal tenant's safety, security, or proper functioning. The lease language also outlines

[6] In March 2017, GSA's Office of Leasing issued Leasing Alert LA–FY17–06 requiring Lease Contracting Officers (LCOs) to determine whether the ownership of leased space is identified as a foreign-owned entity and to notify the client agency in such instances, so that the agency can take any needed security mitigation measures. The Leasing Alert outlined the procedures to make this determination which involved a review of the entity's SAM registration; the Leasing Alert also required this review for all lease procurements and novations, regardless of the Facility Security Level (FSL).

In October 2018, GSA added a ''Foreign Ownership and Financing Representation,'' to be included with all Request for Lease Proposals (RLP) packages issued for prospectus-level lease projects. This ''paper'' representation required the offeror to confirm both foreign ownership and foreign financing.

[7] GSA's Leasing Desk Guide, *https://www.gsa.gov/real-estate/real-estate-services/leasing-policy-procedures/policy-and-tools/policy/leasing-desk-guide-and-other-policy-information/leasing-desk-guide-pdf.*

[8] GSA's Leasing Alerts and Lease Acquisition Circulars (LAC), *https://www.gsa.gov/real-estate/real-estate-services/leasing-policy-procedures/policy-and-tools/policy/leasing-desk-guide-and-other-policy-information/leasing-alerts-and-lease-acquisition-circulars-lac.*

[9] The Desk Guide chapters contain authorities, policies, technical and procedural guides, and administrative limitations governing the acquisition by lease of real property. Chapter 19 is specific to security requirements.

[10] A Federal committee dedicated to the protection of Federal civilian facilities in the United States. It has 21 primary member agencies and 30 associate member agencies. The ISC has developed standards applicable to all civilian Federal facilities, including leased facilities.

[11] GSA's Leasing Alerts and Lease Acquisition Circulars (LAC) LA–21–10 *https://www.gsa.gov/cdnstatic/Real_Estate_Acquisitions/Leasing_Alert_21-10_Revisions_to_FSL_Templates_and_SecUP_rev__8112021c.pdf.*

[12] LA–FY18–05, *Cybersecurity Measures for Leased Facilities, https://www.gsa.gov/cdnstatic/Real_Estate_Acquisitions/Leasing_Alert_%28LA-FY18-05%29_-_Cybersecurity_Measures_for_Leased_Facilities.pdf.*

recommended cybersecurity measures that lessors are encouraged to follow.

Lessors are already currently required to report certain ownership information. As previously outlined, GSA currently collects foreign ownership information for potential lessors, including immediate or highest-level owners, and provides such information to tenant agencies. While this rule requires additional information related to the lessor's beneficial ownership, the review of owner detail has already been in place and is a requirement Federal lessors are familiar with.

(2) GSA Leasing—General Security Framework

As outlined in the GSA Leasing Desk Guide, the facility security level (FSL) [13] for each space requirement is set by the Department of Homeland Security—Federal Protective Service (FPS) and the client agency, in consultation with the GSA as part of the requirements development phase of a lease acquisition. If the client agency and FPS have not already conferred, GSA must coordinate with the necessary parties to set the appropriate level of security before the solicitation is drafted. The Desk Guide states that GSA Leasing acquisition members must maintain contact as necessary with the appropriate FPS inspector throughout the lease administration. The facility security level designation does not change solely based on lessor ownership information collected via this rule.

(3) GSA Leasing—Determining Countermeasures

GSA follows the Interagency Security Committee (ISC) provided standard for Physical Security Criteria (PSC) for Federal Facilities.[14] This standard establishes baseline physical security measures for each designated FSL. This standard defines the process for determining the appropriate security measures; it also covers any uncommon measures required to address the unique risks at a particular facility. The GSA Desk Guide currently uses the PSC to prescribe the process for determining appropriate countermeasures for a facility. Adherence to this process (1) ensures that all security criteria will be considered; (2) defines the relationship between the levels of risk determined for each undesirable event and; (3) mitigates risk through countermeasures that provide a commensurate Level of Protection (LOP). The lessor ownership information does not affect the PSCs for Federal Facilities and therefore GSA does not anticipate this rule to have a significant impact on the security standards used by GSA tenants.

(c) Compliance Plan Estimated Due to Proposed Rule

GSA assumes the following steps would most likely be part of a lessor's plan that would need to be developed by any entity to stay in compliance with the revised representation clause at GSAR 552.270–33:

1. Regulatory Familiarization.

The entity must read and understand the GSAR rules and the resulting necessary actions for compliance.

2. Workforce Training.

The entity must educate its purchasing/procurement professionals [15] to ensure that they are familiar with the revised representation and their disclosure requirements (as applicable).

3. Compliance with the Revised Representation Clause.

The entity must identify and disclose whether the entity does or does not have a beneficial owner of the leased space and, if so, whether that beneficial owner is a foreign person. If an affirmative disclosure is made, and if the Federal lessee is assigning the building or other improvement that will be used for high-security space to a Federal tenant, the Federal tenant shall be notified of the disclosure made in the representation clause prior to award of the lease or approval of the novation agreement.

(d) Benefits

This Act requires the identification of all individuals who own or benefit from partial ownership of a property that will be leased by the federal government for high-security use. The statute is in response to a 2017 Government Accountability Office (GAO) report which indicated that Federal agencies were vulnerable to espionage and other intrusions because foreign actors could gain unauthorized access to spaces used for classified operations or to store sensitive data. Agencies store law enforcement evidence and other sensitive data and are often unaware of foreign ownership of their office spaces. While many of the foreign owners identified in the 2017 GAO report were companies based in allied countries such as Canada, Norway, Japan, or South Korea, other properties were owned and managed by entities based in more adversarial nations. The report noted Chinese-owned properties, in particular, presented security challenges because of the country's proclivity for cyberespionage and the close ties between private sector companies and the Chinese Government. The GAO report highlighted the dangers posed by these properties, indicating that ''leasing space in foreign-owned buildings could present security risks such as espionage, unauthorized cyber and physical access to the facilities, and sabotage.''

The United States faces an expanding array of foreign intelligence threats by adversaries who are using increasingly sophisticated methods to harm the Nation. Threats to the United States posed by foreign intelligence entities are becoming more complex and harmful to U.S. interests. Foreign intelligence actors are employing innovative combinations of traditional spying, economic espionage, and supply chain and cyber operations to gain access to critical infrastructure and steal sensitive information and industrial secrets. The exploitation of key supply chains by foreign adversaries represents a complex and growing threat to strategically important U.S. economic sectors and critical infrastructure.[16]

Additionally, by requiring ''Beneficial Owner'' information in the representation clause, GSA will benefit by better understanding how an individuals' ownership position can provide them access that could prove problematic for certain agencies. Congress underscored that money launderers and others involved in commercial activity intentionally conduct transactions through corporate structures in order to evade detection, and may layer such structures across various secretive jurisdictions such that each time an investigator obtains ownership records for a domestic or foreign entity, the newly identified entity is yet another corporate entity, necessitating a repeat of the same process.[17] The ability to engage in activity and obtain financial services in the name of a legal entity without disclosing the identities of the natural persons who own or control the entity—the natural persons whose interests the legal entity most directly serves—enables those natural persons to conceal their interests. And as the Treasury's Financial Crimes Enforcement Network (FinCEN) has noted previously, such concealment ''facilitates crime, threatens national security, and

[13] A categorization based on the analysis of several security-related facility factors.

[14] See Cybersecurity and Infrastructure Security Agency (CISA) ISC Standard, March 2021, *https://www.cisa.gov/isc-policies-standards-best-practices.*

[15] GSA estimates that the purchasing/procurement professional requiring training as a result of this rule on average would be equal to a mid-career professional. The equivalent labor category used to capture cost estimates therefore is a GS–12 Step 5, or Journeyman Level 1.

[16] *National Counterintelligence Strategy of the United States of America 2020–2022.*

[17] Corporate Transparency Act Section 6402(4).

jeopardizes the integrity of the financial system.'' [18] The goal of the Act is to close security loopholes by directing the GSA to design a verification system that identifies a property's owners if the space would be used for high-security purposes. While GSA and other Federal agencies have made positive changes in response to GAO's 2017 report, this rule will help support current best practices being followed more uniformly throughout the Federal government.

Finally, this rule ensures that GSA will have the ability to obtain information on foreign ownership and provide it to relevant Federal tenants.

(e) Public Costs

During the first and subsequent years after publication of the rule, lessors will need to learn about the representation clause and its requirements. GSA estimates this cost by multiplying the time required to review the regulation and guidance implementing the rule by the estimated compensation of a purchasing/procurement mid-career professional. The equivalent labor category used to capture cost estimates therefore is a GS–12 Step 5.

A. To estimate the aggregate burden to Government lessors of complying with the rule, the number of lessors that will be impacted was calculated using numbers pulled from GSA's records and databases.[19] As of August 2021, GSA has approximately 7,860 leases totaling approximately 183,000,000 in Rentable Square Footage (RSF) and approximately $5,600,000,000 in annual rent ($2,800,000,000 of that total represents small entities). Of the 7,860, approximately 1,263 [20] (or 16 percent) of the leases are for high-security lease space (lease space in a facility with a security level of III, IV, or V) totaling approximately 87,000,000 in RSF and approximately $3,000,000,000 in annual rent. Approximately 68 percent [21] of the leasing entities are small entities. High-security leases with these small entities represents $1,370,000,000 in annual rent covering approximately 37,000,000 RSF.

B. GSA also delegates leasing authority to several agencies, which are required to follow GSA's policies. GSA estimates there are 5,000 [22] buildings represented by these agencies with Delegated Leasing Authority from GSA. GSA does not have data available that identifies which of these are for high-security lease space. GSA assumes that these delegated agencies have a similar profile to GSA's for high-security leased space to total portfolio space, *i.e.,* 16 percent. This would bring the total number of high-security lease space for delegated agencies to 800 (5,000 × 16 percent). GSA also assumes the same profile for small entities of 68 percent.

C. Based on historical data maintained by GSA's Office of Leasing, GSA estimates that 6 percent of its high-security leased space will be solicited for a new contract each year (6 percent of 1,263 = 76 leases). These solicitations result from a mix of expiring high-security leases or new requirements for high-security facilities. GSA assumes these trends will continue for the time horizon outlined by this regulatory impact. Based on historic bid rates and high current vacancy levels, GSA further estimates that 3 lessors will make offers for these high-security lease procurement for a total of 228 offers (76 high-security leases awarded * 3 lessors competing for each solicitation. 76 * 3 = 228) GSA assumes the same profile for delegated facilities.

D. Since 2014, GSA has averaged approximately 31 renewal options per year for high-security leases (equal to approximately 17 percent of all renewals options during the same period) and averaged approximately 106 extensions for existing high-security leases (also equal to approximately 17 percent of all extensions during the same period). GSA assumes the same trend will continue in subsequent years. GSA assumes the same profile for delegated facilities.

E. GSA processed 380 novations from May 1, 2020 to April 30, 2021 [23] [24] (therefore approximately 5 percent of leases resulted in a novation (380/7,860)). GSA does not have data on how many of those were related to FSL III, IV, or V. GSA will assume 16 percent of those novations were for FSL III, IV, or V leases. Therefore, it is assumed 61 novations were processed for high-security leases in the last year.

A breakdown is provided in the table below.

Par above		GSA	Delegated authority agencies
A,B	Leased Space	7,860	5,000
A,B	High-Security (HS) Space Leases (16 percent)	1,263	800
	Total HS Portfolio	1,263	800
	Existing HS Lease Baseline	1,263	800
	Combined HS Lease Baseline	2,063 (1,263 + 800)	
C	New Procurements (6 percent HS)	76	48
C	New Offers (x3)	228	144
	Total New Responses	228	144
D	Renewals (17 percent HS)	31	3
D	Extensions (17 percent HS)	106	3
E	Novations (5 percent Leases)	380	38
E	High-Security Space Novations (16 percent)	61	6
	Total HS Novations	61	6
	New HS Lease Baseline	426 (228+31+106+61)	156 (144+3+3+6)
	Combined New HS Lease Baseline	582 (426 + 156)	

[18] *Notice of Proposed Rulemaking: Customer Due Diligence Requirements for Financial Institutions,* 79 FR 45151, 45153 (August 4, 2014).

[19] If not otherwise stated, numbers related to leases are provided by the GSA Office of Leasing through surveying their internal databases.

[20] The GSA Office of Leasing provided this number by surveying their internal database.

[21] This information is based on internal inventory data sources provided by the GSA Office of Leasing.

[22] This information is based on internal inventory data sources provided by the GSA Office of Leasing.

[23] This information is based on internal inventory data sources provided by the GSA Office of Leasing.

[24] GSA does not have data on how many novations other agencies with Delegated Leasing Authority processed.

Steps to Compliance:

1. Regulatory Familiarization

Below is a list of compliance activities related to regulatory familiarization that GSA anticipates will occur:

a. Familiarization With GSAR 552.270–33, Foreign Ownership and Financing Representation for High-Security Leased Space

i. GSA estimates that it will take existing high-security lessors approximately 0.5 hours [25] each to familiarize themselves with the revised GSAR representation. Therefore, GSA calculated the total estimated cost for this part of the rule to be *$86,900* [26] *(= 0.5 hours × $84.16* [27] *× 2,063).* Of the 2,063 lessors impacted by this part of the rule, GSA assumes that 68 percent, or approximately 1,403 lessors, are small entities.

After the initial familiarization in the first year for each current awardee or subsequent awardee, GSA estimates it will take 15 minutes (0.25 hours [28]) to stay familiar with the representation. Therefore, GSA calculated the total estimated cost for this part of the rule to be *$43,400 (= 0.25 hours × $84.16 × 2,063).*

ii. GSA estimates that new high-security lessors each year will take approximately 0.5 hours [29] each to familiarize themselves with the revised GSAR representation. Therefore, GSA calculated the total estimated cost for this part of the rule to be *$24,500 (= 0.5 hours × $84.16 × 582).* Of the 582 lessors impacted by this part of the rule, GSA assumes that 68 percent, or approximately 396 lessors, are small entities.

The total estimated cost to become familiar with the revised representation clause (GSAR 552.270–33) is estimated to be *$86,900* for the existing high-security lessors. In subsequent years, this cost is estimated to be *$68,000* for new high-security lessors annually.

2. Implementation of Workforce Training

The entity must educate its purchasing/procurement professionals to ensure that they are familiar with the representation and their disclosure requirements (as applicable).

a. GSA estimates that it will take existing high-security lessors approximately 3 hours [30] each to train their workforce on the revised representation clause at GSAR 552.270–33. Therefore, GSA calculated the total estimated cost for this part of the rule to be *$521,000 (= 3 hours × $84.16 × 2,063).* Of the 1,263 lessors impacted by this part of the rule, GSA assumes that 68 percent, or approximately 1,403 lessors, are small entities.

After the initial training in the first year for each current awardee or subsequent awardee, GSA estimates it will take 15 minutes (0.25 hours [31]) to conduct continuing additional workforce training. Therefore, GSA calculated the total estimated cost for this part of the rule to be *$43,400 (= 0.25 hours × $84.16 × 2,063).*

b. GSA estimates that new high-security lessors each year will take approximately 3 hours each to train their workforce on the representation clause at GSAR 552.270–33. Therefore, GSA calculated the total estimated cost for this part of the rule to be *$147,000 (= 3 hours × $84.16 × 582).* Of the 582 lessors impacted by this part of the rule, GSA assumes that 68 percent, or approximately 396 lessors, are small entities.

The total estimated cost to implement workforce training for the revised representation clause (GSAR 552.270–33) is estimated to be *$521,000* for the existing high-security lessors. In subsequent years, this cost is estimated to be *$190,000* for new high-security lessors annually.

3. Compliance With Clauses

a. GSAR 552.270–33, Foreign Ownership and Financing Representation for High-Security Leased Space

i. GSA estimates that it will take existing high-security lessors approximately 0.5 hours [32] each to complete the additional disclosure at paragraph (e)(1) of the representation clause. Therefore, GSA calculated the total estimated cost for this part of the rule to be *$86,800 (= 0.5 hours × $84.16 × 2,063).* Of the *2,063* lessors impacted by this part of the rule, GSA assumes that 68 percent, or approximately 1,403 lessors, are small entities.

ii. GSA estimates that new high-security lessors each year will take approximately 0.5 hours each to complete the additional disclosure at paragraph (e)(1) of the representation clause. Therefore, GSA calculated the total estimated cost for this part of the rule to be *$24,500 (= 0.5 hours × $84.16 × 582).* Of the 582 lessors impacted by this part of the rule, GSA assumes that 68 percent, or approximately 396 lessors, are small entities.

iii. GSA further estimates that of the existing high-security lessors, 10 percent [33] (or 206 lessors) will respond affirmatively to paragraph (e)(1) of the representation clause that the offeror ''does'' have a ''beneficial owner'' and will be required to complete the additional information at paragraph (e)(2). GSA estimates that it will take these offerors an additional 6 hours [34] to complete those various sections of the representation clause. Therefore, GSA calculated the total estimated cost for this part of the rule to be *$104,000 (= 6 hours × $84.16 × 206).* Of the 206 lessors impacted by this part of the rule, GSA assumes that 68 percent, or approximately 140 lessors, are unique small entities.

iv. GSA estimates that of the new high-security lessors each year, 10 percent [35] (or 58 lessors) will respond

[25] The hours estimated are an assumption based on historical familiarization hours and subject matter expert judgement. Subject matter experts include representatives from GSA's Office of Leasing, including Realty Specialists and Leasing Contracting Officers.

[26] Totals are rounded.

[27] This hourly rate, $84.16, is the 2021 GS rate for a GS–12 Step 5 of $42.08 per hour (using the rate for the rest of the United States) adjusted upward by 100 percent to account for fringe benefits and overhead.

[28] The hours estimated are an assumption based on historical familiarization hours and subject matter expert judgement. Subject matter experts include representatives from GSA's Office of Leasing, including Realty Specialists and Leasing Contracting Officers.

[29] The hours estimated are an assumption based on historical familiarization hours and subject matter expert judgement. Subject matter experts include representatives from GSA's Office of Leasing, including Realty Specialists and Leasing Contracting Officers.

[30] The hours estimated are an assumption based on historical familiarization hours and subject matter expert judgement. Subject matter experts include representatives from GSA's Office of Leasing, including Realty Specialists and Leasing Contracting Officers.

[31] The hours estimated are an assumption based on historical familiarization hours and subject matter expert judgement. Subject matter experts include representatives from GSA's Office of Leasing, including Realty Specialists and Leasing Contracting Officers.

[32] The hours estimated are an assumption based on historical familiarization hours and subject matter expert judgement. Subject matter experts include representatives from GSA's Office of Leasing, including Realty Specialists and Leasing Contracting Officers.

[33] The amount of lessors impacted is an assumption based on subject matter expert judgment.

[34] The hours estimated are an assumption based on historical familiarization hours and subject matter expert judgement. Subject matter experts include representatives from GSA's Office of Leasing, including Realty Specialists and Leasing Contracting Officers.

[35] The amount of lessors impacted is an assumption based on subject matter expert judgment.

affirmatively to paragraph (e)(1) of the representation clause that the offeror ''does'' have a ''beneficial owner'' and will be required to complete the additional information at paragraph (e)(2). Thus, approximately 58 lessors (10 percent of 582) need to fully complete GSAR 552.270–33. Therefore, GSA calculated the total estimated cost for this part of the rule to be *$28,800 (= 6 hours × $84.16 × 58).* Of the *58* lessors impacted by this part of the rule, GSA assumes that 68 percent, or approximately 39 lessors, are small entities.

After the existing and new high-security lessors complete the representations, GSA estimates it will take 15 minutes (0.25 hours [36]) to update any information as necessary and as required annually. Therefore, GSA calculated the total estimated cost for this part of the rule to be *$47,700 (= [0.25 hours × $84.16 × 2,063] + [0.25 × $84.16 × 206]).*

The total estimated cost to complete the representation clause is estimated to be *$191,000* the existing high-security lessors. In subsequent years, this cost is estimated to be *$101,000* for new high-security lessors annually.

4. Public Total Costs

The total cost of the above Cost Estimate is *$799,000* in the first year after publication.

The total cost of the above Cost Estimate in subsequent years is *$359,000* annually.

The following is a summary of the estimated costs calculated for a 10 year time horizon in perpetuity at a 3- and 7-percent discount rate:

Summary	Total costs
Present Value (3 percent)	$3,491,000
Annualized Costs (3 percent)	409,000
Present Value (7 percent)	2,934,000
Annualized Costs (7 percent)	418,000

GSA notes that this rule does not authorize GSA lease contracting officers to use the information disclosed by offerors as a differentiating factor for selection of a lease award, nor does it authorize GSA to terminate a lease, prevent a novation, or otherwise decline to make an award based on the disclosure. As such, GSA estimates that this rule will not result in these activities, and therefore no moving costs have been included in this regulatory impact analysis.

[36] The hours estimated are an assumption based on historical familiarization hours and subject matter expert judgement. Subject matter experts include representatives from GSA's Office of Leasing, including Realty Specialists and Leasing Contracting Officers.

GSA acknowledges that there is uncertainty underlying these estimates, including elements for which an estimate is unavailable given inadequate information. As more information becomes available, including through comment in response to this document, GSA will seek to update these estimates which could increase the estimated costs.

(f) Government Cost Analysis

During the first and subsequent years after publication of the rule, leasing acquisition members (which includes a combination of Leasing Contracting Officers, Lease Administration Managers, Realty Specialists, and General Counsel) will need to learn about the representation clause and its requirements. GSA estimates this cost by multiplying the time required to review the regulations and guidance implementing the rule by the estimated compensation, on average, of a GS–12 leasing acquisition member. GSA assumes that leasing acquisition members will, on average, stay consistent in subsequent years. Numbers and assumptions apply to delegated agencies as well.

GSA anticipates several areas of impact as a result of this rule. These impacts mirror the public impacts and will appear as regulatory familiarization, workforce training, and time to review compliance with clauses. These costs are justified in light of the compelling national security objective that this rule will advance.

For consistency, the number of leases to be reviewed match the numbers in the ''Existing HS Lease Baseline'' row (2,063 combined) and ''New annual Lease Baseline'' row (582 combined) found in table in section VI.(e).

1. Regulatory Familiarization

a. GSA estimates that it will take approximately 722 leasing acquisition members 0.5 hours to become familiar with the revised GSAR 552.270–33 representation. Therefore, GSA calculated the total estimated cost for this part of the rule to be *$30,400* [37] *(= 0.5 hours × $84.16 × 722).*

After the initial familiarization, GSA estimates it will take 15 minutes (0.25 hours) to stay familiar with the revised representation in subsequent years. Therefore, GSA calculated the total estimated cost for this part of the rule to be *$15,200 (= 0.25 hours × $84.16 × 722).*

[37] All totals in the Government Cost Analysis section are rounded.

2. Workforce Training

The Government must educate its leasing acquisition members to ensure that they are familiar with the representation and clause and how to review and act on the submitted information, access requests, and written procedures.

a. GSA estimates that it will take approximately 722 leasing acquisition members 0.5 hour to complete training related to the revised GSAR 552.270–33 representation. Therefore, GSA calculated the total estimated cost for this part of the rule to be *$30,400 (= 0.5 hours × $84.16 × 722).*

After the initial training, GSA estimates it will take 15 minutes (0.25 hours) to maintain training related to the revised representation. Therefore, GSA calculated the total estimated cost for this part of the rule to be *$15,200 (= 0.25 hours × $84.16 × 722).*

3. Review of Compliance With Clauses

a. GSAR 552.270–33, Foreign Ownership and Financing Representation for High-Security Leased Space

i. GSA estimates that it will take leasing acquisition members approximately 10 minutes (0.17 hours) to review the representation at paragraph (e)(1) of the revised representation clause at GSAR 552.270–33 for existing high-security lessors. Therefore, GSA calculated the total estimated cost for this part of the rule to be *$29,500 (= 0.17 hours × $84.16 × 2,063).*

ii. GSA estimates that for new high-security lessors each year, it will take leasing acquisition members approximately 10 minutes (0.17 hours) to review the representation at paragraph (e)(1) of the revised representation clause GSAR 552.270–33. Therefore, GSA calculated the total estimated cost for this part of the rule to be *$8,300 (= 0.17 hours × $84.16 × 582).*

iii. GSA estimates that for existing high-security lessors, 10 percent (or 206 lessors) will respond affirmatively to paragraph (e)(1) of the representation clause that the offeror ''does'' have a ''beneficial owner'' and will be required to complete the additional information at paragraph (e)(2). GSA estimates that it will take leasing acquisition members 2.5 hours to complete the reviews on those various sections of the revised representation clause, notify the Federal tenant of the building or other improvement of any security concerns and necessary mitigation measures (if any) prior to award or approval of a novation agreement. Therefore, GSA

calculated the total estimated cost for this part of the rule to be *$43,300 (= 2.5 hours × $84.16 × 206).*

iv. GSA estimates 10 percent, or 58 lessors, of new high-security lessors each year will respond affirmatively to paragraph (e)(1) of the representation clause that the offeror ''does'' have a ''beneficial owner'' and will be required to complete the additional information at paragraph (e)(2). GSA estimates that it will take leasing acquisition members 2.5 hours to complete the reviews on those various sections of the revised representation clause, notify the Federal tenant of the building or other improvement of any security concerns and necessary mitigation measures (if any) prior to award or approval of a novation agreement. Therefore, GSA calculated the total estimated cost for this part of the rule to be *$12,200 (= 2.5 hours × $84.16 × 58).*

4. Reduced Competition

GSA acknowledges the representation clause may lead to reduced competition. Some lessors may choose to exit the Federal market, particularly lessors that primarily lease to the private sector, because of the additional disclosure requirements, and the subsequent reduced level of competition may increase prices. However, estimated costs faced by contractors represent a small fraction of lease payments, and therefore GSA expects effects along these lines to be minimal.

5. Government Total Costs

The total cost of the above Cost Estimate is *$133,700* in the first year after publication. The total cost of the above Cost Estimate in subsequent years is *$51,000* annually.

The following is a summary of the estimated costs calculated for a 10 year time horizon at a 3- and 7-percent discount rate:

Summary	Total costs
Present Value (3 percent)	$515,000
Annualized Costs (3 percent)	60,400
Present Value (7 percent)	435,000
Annualized Costs (7 percent)	62,000

GSA notes that this proposed rule does not authorize GSA lease contracting officers to use the information disclosed by offerors as a differentiating factor for selection of a lease award, nor does it authorize GSA to terminate a lease, prevent a novation, or otherwise decline to make an award based on the disclosure. As such, GSA estimates that this rule will not result in these activities, and therefore no moving costs have been accounted for in this regulatory impact analysis.

6. Overall Total Costs

The overall total cost of the above Cost Estimate, including both Public and Government costs, is *$932,000* in the first year after publication.

The overall total cost of the above Cost Estimate, including both Public and Government costs in subsequent years, is *$410,000* annually.

The following is a summary of the estimated overall total costs calculated for a 10 year time horizon at a 3- and 7-percent discount rate inclusive of both Public and Government costs:

Summary	Total costs
Present Value (3 percent)	$4,000,000
Annualized Costs (3 percent)	469,000
Present Value (7 percent)	3,400,000
Annualized Costs (7 percent)	479,000

(g) Analysis of Alternatives

Alternative 1: GSA could take no regulatory action to implement this statute. However, this alternative would not provide any implementation and enforcement of the important national security measures imposed by the law. Moreover, the general public would not experience the benefits of improved national security resulting from the rule as detailed above in Section VI.(d). As a result, we reject this alternative.

Alternative 2: GSA could take a more stringent approach to the requirements of the Act and apply the new clauses to not only all GSA leases and delegated leases for FSL III, IV, or V space but for all FSL designations. However, given the relatively low levels of risk at those facilities, as described by the ISC, compared with the costs and burden applying this revised representation clause clause,[38] no additional benefit would be gained. As a result, we reject this alternative.

GSA also considered issuing an acquisition letter, but concluded the best alternative was to issue this proposed rule directly implementing the statute and allowing for public comment, in addition to being consistent with previous rulemaking (GSAR 2021–G527).

(h) Specific Questions for Comment

To understand the exact scope of the impact of this rule and how this impact could be affected, GSA welcomes input on the following assumptions and questions regarding anticipated impact on affected parties.

Assumption 1: As previously stated, GSA assumes that most Federal lessors maintaining high-security leased space or Federal lessors that are competing for solicitations for high-security leased space are already familiar with the majority of the requirements of this rule, or, similarly, will not find the requirements of this proposed rule as anything significantly more than what is currently expected. GSA previously implemented ownership disclosures requirements through internal policy,[39] GSA's Request for Lease Proposals (or solicitations), GSA's guidance through its public-facing Leasing Desk Guide,[40] Leasing Alerts and Lease Acquisition Circulars,[41] and GSAR Case 2021–G527.

Question 1: If this assumption is not valid, to what extent are the requirements in this rule, specifically the revised elements of GSAR 552.270–33, significantly different from what GSA has currently been doing as part of its procedures for foreign ownership disclosure?

Assumption 2: GSA estimates that this rule will impact mainly the Federal lessor industry.

Question 2: If this assumption is not valid, is there another industry(s) to which this rule will cause significant impact or disruption?

Assumption 3: The impact of this rule will not significantly change the way current Federal lessors interact with GSA.

Question 3: If this assumption is not valid, to what extent will this rule, specifically the revised elements of GSAR 552.270–33, change how you interact with GSA?

Assumption 4: The impact of this rule will not significantly reduce the number of lessors competing for High-Security Leased Space solicitations.

Question 4: If this assumption is not valid, to what extent will this rule, specifically the revised elements of GSAR 552.270–33, reduce the

[38] As this Regulatory Impact Analysis only considers 2,063 high-security leases (or approximately 16% of the GSA leasing portfolio), it's reasonable to estimate that if the entire portfolio was included, costs could be approximately 5X more costly than currently shown.

[39] In March 2017, GSA's Office of Leasing issued Leasing Alert LA–FY17–06 requiring Lease Contracting Officers (LCOs) to determine whether the ownership of leased space is identified as a foreign-owned entity and to notify the client agency in such instances, so that the agency can take any needed security mitigation measures. The Leasing Alert outlined the procedures to make this determination which involved a review of the entity's SAM registration; the Leasing Alert also required this review for all lease procurements and novations, regardless of the Facility Security Level (FSL). In October 2018, GSA added a ''Foreign Ownership and Financing Representation,'' to be included with all Request for Lease Proposals (RLP) packages issued for prospectus-level lease projects. This ''paper'' representation required the offeror to confirm both foreign ownership and foreign financing

[40] GSA's Leasing Desk Guide.

[41] GSA's Leasing Alerts and Lease Acquisition Circulars (LAC).

likelihood of you—lessor to the Federal Government for High-Security Leased Space—from not competing for future solicitations of High-Security Leased Space?

Assumption 5: The compliance activities, and associated costs, estimated by GSA are stated at Section VI.(e).

Question 5: Is there a compliance activity that GSA has failed to consider? If so, please specify the activity, explain the activity, describe the impact of the activity, and please estimate the annual cost of such activities and subsequent yearly activity costs.

Question 6: Is there a compliance activity that GSA has noted that is significantly understated (in terms of annual and subsequent costs)? If so, which compliance activity and what specifically was understated? Please explain how the compliance activity should be estimated.

Assumption 7: Other agencies relying upon GSA's leasing authority have similar profiles of high security leases in their inventory.

Question 7: What information is available to better estimate high security leases in other agency inventories?

Assumption 8: GSA sufficiently detailed all compliance requirements for the rule.

Question 9: What additional information or guidance do you view as necessary to effectively comply with this rule?

Question 10: What other challenges do you anticipate facing in effectively complying with this rule?

Question 11: What thoughts or observations would you like to share regarding foreign ownership, including beneficial ownership, for GSA to consider in subsequent rule-making?

Assumption 9: GSA's ''beneficial owner'' definition is not less stringent than the SEC definition (17 CFR 204.13d–3).

Question 12: Is this definition less stringent than the definition provided by the Secure Federal LEASEs Act definition? If so, how?

Question 13: Is there a different definition of ''beneficial owner'' that GSA should use as part of the representation clause at GSAR 552.270–33? If so, what is the definition and why should it be used instead of the definition GSA has already drafted into GSAR 552.270–33?

VII. Executive Order 12866 and 13563

Executive Orders (E.O.s) 12866 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, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule is anticipated to be a significant regulatory action and, therefore, has been reviewed in accordance with section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. See Section VI for a regulatory impact analysis of the rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a ''major 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. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rule is anticipated not to be a ''major rule'' under 5 U.S.C. 804(2).

IX. Regulatory Flexibility Act

The General Services Administration 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.* However, an Initial Regulatory Flexibility Analysis (IRFA) has been performed, and is summarized as follows:

The purpose of this rule is to implement certain requirements outlined in the Secure Federal LEASEs Act (Pub. L. 116–276) into the GSAR.

The objective of the rule is to prescribe appropriate policies and procedures to address the risks of foreign ownership of Government-leased real estate and requires the disclosure of ownership information for high-security space leased to accommodate a Federal agency. Representation clause GSAR 552.270–33 (representation) is being revised to include beneficial owner disclosures. The representation will be required in all novations, solicitations and contracts for leased space that (1) will be occupied by Federal employees for nonmilitary activities; and (2) have a facility security level of III, IV, or V.

The representation requirement at GSAR 552.270–33 will be incorporated into all new lease awards, options exercised for current leases, lease extensions, and ownership changes for high-security leased space. Except where otherwise provided, the revised representation statutory disclosure requirements shall apply with respect to any lease or novation agreement entered into on or after December 31, 2022, involving high-security leased space. That includes new, replacing, succeeding, and superseding leases, renewal options, extensions, and novations. This includes actions involving small entities. The representation requires offerors for high-security leased space to identify whether the offeror or lessor does or does not have a beneficial owner, and, if so, disclosure whether the beneficial owner is a foreign person. Further, if the offeror or lessor does represent it has a beneficial owner, they must represent the legal name of the person, their current residential or business street address, and the identifying number or document that verifies identity as a United States person, foreign person, or foreign entity. Awardees will also be required to re-represent on an annual basis. This representation also applies upon change of ownership/novations.

As of August 2021, GSA has approximately 7,860 leases in total. Approximately 68 percent (5,345) of leasing entities were small entities. This information is based on internal inventory data sources. Approximately 1,263 of GSA portfolio leases are for high-security lease space (lease space in a facility with a security level of III, IV, or V). 76 leases per year are estimated to be solicited for new high-security space procurements. These solicitations result from a mix of expiring high-security leases or new requirements for high-security facilities. Using the approximation above (68 percent), GSA estimates that for the 1,263 lessors already maintaining leased space at a Level III, IV, or V secure facility approximately 859 will be small entities (1,263*68 percent). If GSA includes agencies with delegated leasing authority, the approximate number of total leases at a Level III, IV, or V is 2,063. This would increase the approximate number of small entities to 1,403 (from 859). For the estimated 76 solicitations in subsequent years, assuming 3 offerors per solicitation, approximately 155 will be submitted by small entities.

This rule does not duplicate, overlap, or conflict with any other Federal rules.

Because of the requirements outlined by the statute, it is not possible to establish different compliance or reporting requirements or timetables that take into account the resources available to small entities or to exempt small entities from coverage of the rule, or any part thereof. However, in order to reduce the burden imposed on the public, GSA is currently reviewing and investigating potential future implementation through electronic means, including externally (System for Award Management) or internally.

Entities that provide affirmative responses when completing the representation at 552.270–33 would be required to provide additional representation information in their offers for high-security leases.

The Regulatory Secretariat Division has submitted a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the

Regulatory Secretariat Division. GSA invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

GSA will also consider comments from small entities concerning the existing regulations in subparts affected by the rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C 610 (GSAR Case 2021–G522) in correspondence.

X. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. Chapter 35) does apply because the rule contains procedures with information collection requirements. The revised GSAR clause 552.270–33 now adds the requirement that offerors for high-security leased space identify whether the offeror does or does not have a beneficial owner(s), and if so, if the beneficial owner(s) is a foreign person(s).

The revised disclosure imposes additional information collection requirements to the paperwork burden previously approved under the existing OMB Control Number 3090–0324.

The annual reporting burden is estimated as follows:

1. Initial Disclosure

Baseline Representation

Estimated annual responses: 582.

Estimated hours per response: 0.5.

Additional Representation

Estimated annual responses: 58.

Estimated hours per response: 6.

Total Initial Response Burden Hours: 639.

2. Annual Updates

Estimated annual responses: 582.

Estimated hours per response: 0.10.

Total Update Response Burden Hours: 58.

Public comments are particularly invited on: Whether this collection of information is necessary; whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

List of Subjects in 48 CFR Part 552

Government procurement.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy, General Services Administration.

Therefore, GSA proposes to amend 48 CFR part 552 as set forth below:

PART 552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 1. The authority citation for 48 CFR part 552 continues to read as follows:

Authority: 40 U.S.C. 121(c).

■ 2. Amend section 552.270–33 by—

■ a. Revising the clause heading and the date of the clause;

■ b. In paragraph (a):

■ i. Adding the definitions ''Beneficial Owner'', ''Control'', and ''Covered entity'' in alphabetical order;

■ ii. Revising the definition of ''Financing''; and

■ iii. In the definition of ''Foreign entity'', revising paragraph (ii);

■ c. Removing from paragraph (b) the words ''shall complete'' and adding ''shall complete and provide'' in their place;

■ d. In paragraph (c)(2):

■ i. Removing from the introductory text the words ''each entity'' and adding ''each person or entity'' in their place; and

■ ii. Revising the table;

■ e. Removing paragraphs (c)(3) through (5);

■ f. Removing from paragraph (d)(1) the words ''another entity'' and adding ''owners (person or entity)'' in their place;

■ g. Revising the table in paragraph (d)(2);

■ h. Removing paragraphs (d)(3) through (5);

■ i. Redesignate paragraph (e) as paragraph (f);

■ j. Adding a new paragraph (e); and

■ k. In the newly designated paragraph (f)(3):

■ i. Removing from the introductory text the reference ''(e)(1) or (2)'' and adding ''(f)(1) or (2)'' in its place; and

■ ii. Revising the table.

The additions and revisions read as follows:

552.270–33 Foreign Ownership and Financing Representation for High-Security Leased Space.

* * * * *

Foreign Ownership and Financing Representation for High-Security Leased Space (DATE)

(a) * * *

Beneficial Owner means, with respect to a covered entity, an individual who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise—

(i) Exercises substantial control over the covered entity; or

(ii) Owns or controls not less than 25 percent of the ownership interests of the covered entity.

Control means, with respect to a covered entity:

(i) Having the authority or ability to determine how a covered entity is utilized; or

(ii) Having some decision-making power for the use of a covered entity.

Covered entity means:

(i) A person, corporation, company, business association, partnership, society, trust, or any other nongovernmental entity, organization, or group; or

(ii) Any governmental entity or instrumentality of a government.

Financing means the process of raising, receiving, or providing funds, such as through debt or equity, for purposes of meeting the requirements of the Lease, including, but not limited to, acquisition, maintenance, or construction of, or improvements to, the property.

Foreign entity * * *

(ii) Government or governmental instrumentality that is not the United States or a state, local government, tribe, or territory within the United States.

* * * * *

(c) * * *

(2) * * *

Legal name (do not use a ''doing business as'' name).	
Unique entity identifier (if available).	
Physical address (including country).	
Status of Immediate Owner: United States person, foreign person, or foreign entity.	
Identifying number or document that verifies status as a United States person, foreign person, or foreign entity.	

(d) * * *

(2) * * *

Legal name (do not use a ''doing business as'' name).	
Unique entity identifier (if available).	
Physical address (including country).	
Status of Highest-level Owner: United States person, foreign person, or foreign entity].	
Identifying number or document that verifies status as a United States person, foreign person, or foreign entity.	

(e) *Beneficial owner.* (1) The Offeror or Lessor represents that it □ does or □ does not have a beneficial owner.

(2) If the Offeror or Lessor indicates ''does'' in paragraph (e)(1) of this clause, then enter the following information for the beneficial owner. If the Offeror or Lessor has more than one beneficial owner (*e.g.,* joint venture), then the Offeror or Lessor shall provide the information for each person.

Legal name (do not use a ''doing business as'' name).	
Unique entity identifier (if available).	
Physical address (Including country).	
Status of Beneficial Owner: United States person, foreign person, or foreign entity.	
Identifying number or document that verifies status as a United States person, foreign person, or foreign entity.	

(f) * * *

(3) * * *

Legal name (do not use a ''doing business as'' name).	
Unique entity identifier (if available).	
Physical address (including country).	
Status of Financing Entity: United States person, foreign person, or foreign entity.	
Identifying number or document that verifies status as a United States person, foreign person, or foreign entity.	

* * * * *

[FR Doc. 2021–27443 Filed 12–23–21; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 224

[Docket No. 211217–0264; RTID 0648–XR120]

Endangered and Threatened Wildlife; 90-Day Finding on a Petition To List the Sunflower Sea Star as Threatened or Endangered Under the Endangered Species Act

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: 90-Day petition finding, request for information, and initiation of status review.

SUMMARY: We, NMFS, announce a 90-day finding on a petition to list the sunflower sea star (*Pycnopodia helianthoides*) as threatened or endangered under the Endangered Species Act (ESA) and to designate critical habitat concurrent with the listing. We find that the petition presents substantial scientific information indicating that the petitioned action may be warranted. Therefore, we are initiating a status review of the species to determine whether listing under the ESA is warranted. To ensure this status review is comprehensive, we are soliciting scientific and commercial information regarding this species.

DATES: Scientific and commercial information pertinent to the petitioned action must be received by February 25, 2022.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–NOAA–NMFS–2021–0130 by the following method:

- *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal. Go to *https://www.regulations.gov* and enter NOAA–NMFS–NOAA–NMFS–2021–0130 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Interested persons may obtain a copy of the petition online at the NMFS website: *https://www.fisheries.noaa.gov/national/endangered-species-conservation/petitions-awaiting-90-day-findings.*

FOR FURTHER INFORMATION CONTACT: Dayv Lowry, NMFS West Coast Region, Protected Resources Division, (253) 317–1764, *David.Lowry@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On August 18, 2021, we received a petition from the Center for Biological Diversity to list the sunflower sea star (*Pycnopodia helianthoides*) as a threatened or endangered species under the ESA and to designate critical habitat concurrent with the listing. The petition asserts that the sunflower sea star is threatened by all five ESA section 4(a)(1) factors: (1) The present or threatened destruction, modification, or curtailment of its habitat or range; (2) overutilization for commercial, recreational, scientific or educational purposes; (3) disease or predation; (4) the inadequacy of existing regulatory mechanisms; and (5) other natural or manmade factors affecting its continued existence. The petition is available online (see **ADDRESSES**).

ESA Statutory, Regulatory, and Policy Provisions and Evaluation Framework

Section 4(b)(3)(A) of the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*), requires, to the maximum extent practicable, that within 90 days of receipt of a petition to list a species as threatened or endangered, the Secretary of Commerce shall make a finding on whether that petition presents substantial scientific or commercial information indicating that the petitioned action may be warranted, and promptly publish such finding in the **Federal Register** (16 U.S.C. 1533(b)(3)(A)). If NMFS finds that substantial scientific or commercial information in a petition indicates the petitioned action may be warranted (a ''positive 90-day finding''), we are required to promptly commence a review of the status of the species concerned, during which we will conduct a comprehensive review of the best available scientific and commercial data. We conclude the review with a finding as to whether, in fact, the petitioned action is warranted within 12 months of receipt of the petition. Because the finding at the 12-month stage is based on a more thorough review of the best available information, as compared to the narrow scope of review at the 90-day stage, a ''positive 90-day'' finding does not prejudge the outcome of the status review.

Under the ESA, a listing determination may address a species, which is defined to also include subspecies and, for any vertebrate species, any distinct population segment (DPS) that interbreeds when mature (16 U.S.C. 1532(16)). A species, subspecies, or DPS is ''endangered'' if it is in danger of extinction throughout all or a significant portion of its range, and ''threatened'' if it is likely to become endangered within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. 1532(6) and (20)). Pursuant to the ESA and our implementing regulations, we determine whether species are threatened or endangered based on any one or a

combination of the following five ESA section 4(a)(1) factors: (1) The present or threatened destruction, modification, or curtailment of its habitat or range; (2) overutilization for commercial, recreational, scientific, or educational purposes; (3) disease or predation; (4) the inadequacy of existing regulatory mechanisms; and (5) other natural or manmade factors affecting its continued existence (16 U.S.C. 1533(a)(1); 50 CFR 424.11(c)).

ESA-implementing regulations issued jointly by NMFS and the U.S. Fish and Wildlife Service (50 CFR 424.14(h)(1)(i)) define ''substantial scientific or commercial information'' in the context of reviewing a petition to list, delist, or reclassify a species as credible scientific or commercial information in support of the petition's claims such that a reasonable person conducting an impartial scientific review would conclude that the action proposed in the petition may be warranted. Conclusions drawn in the petition without the support of credible scientific or commercial information will not be considered substantial information. In reaching the 90-day finding on the petition, we considered the information described in sections 50 CFR 424.14(c), (d), and (g).

Our determination as to whether the petition provides substantial scientific or commercial information indicating that the petitioned action may be warranted depends in part on the degree to which the petition includes the following types of information: (1) Information on current population status and trends and estimates of current population sizes and distributions, both in captivity and the wild, if available; (2) identification of the factors under section 4(a)(1) of the ESA that may affect the species and where these factors are acting upon the species; (3) whether, and to what extent, any or all of the factors alone or in combination identified in section 4(a)(1) of the ESA may cause the species to be an endangered species or threatened species (*i.e.,* the species is currently in danger of extinction or is likely to become so within the foreseeable future), and, if so, how high in magnitude and how imminent the threats to the species and its habitat are; (4) information on adequacy of regulatory protections and effectiveness of conservation activities by States, as well as other parties, that have been initiated or that are ongoing, that may protect the species or its habitat; and (5) a complete, balanced representation of the relevant facts, including information that may contradict claims in the petition. See 50 CFR 424.14(d).

If the petitioner provides supplemental information before the initial finding is made and states that it is part of the petition, the new information, along with the previously submitted information, is treated as a new petition that supersedes the original petition, and the statutory timeframes will begin when such supplemental information is received. See 50 CFR 424.14(g).

We may also consider information readily available at the time the determination is made. We are not required to consider any supporting materials cited by the petitioner if the petitioner does not provide electronic or hard copies, to the extent permitted by U.S. copyright law, or appropriate excerpts or quotations from those materials (*e.g.,* publications, maps, reports, letters from authorities). See 50 CFR 424.14(c)(6) and (h)(1)(ii).

The substantial scientific or commercial information standard must be applied in light of any prior reviews or findings we have made on the listing status of the species that is the subject of the petition (50 CFR 424.14(h)(1)(iii)). Where we have already conducted a finding on, or review of, the listing status of that species (whether in response to a petition or on our own initiative), we will evaluate any petition received thereafter seeking to list, delist, or reclassify that species to determine whether a reasonable person conducting an impartial scientific review would conclude that the action proposed in the petition may be warranted despite the previous review or finding. Where the prior review resulted in a final agency action—such as a final listing determination, a 90-day not-substantial finding, or a 12-month not-warranted finding—a petition will generally not be considered to present substantial scientific and commercial information indicating that the petitioned action may be warranted unless the petition provides new information or analysis not previously considered. See 50 CFR 424.14(h)(1)(iii).

At the 90-day finding stage, we do not conduct additional research, and we do not solicit information from parties outside the agency to help us in evaluating the petition. We accept the petitioners' sources and characterizations of the information presented if they appear to be based on accepted scientific principles, unless we have specific information in our files that indicates the petition's information is incorrect, unreliable, obsolete, or otherwise irrelevant to the requested action. Information that is susceptible to more than one interpretation, or that is contradicted by other available information, will not be dismissed at the 90-day finding stage, so long as it is reliable and a reasonable person conducting an impartial scientific review would conclude it supports the petitioners' assertions. In other words, conclusive information indicating the species may meet the ESA's requirements for listing is not required to make a positive 90-day finding. We will not conclude that a lack of specific information alone necessitates a negative 90-day finding if a reasonable person conducting an impartial scientific review would conclude that the unknown information itself suggests the species may be at risk of extinction presently, or within the foreseeable future.

To make a 90-day finding on a petition to list a species, we first evaluate whether the information presented in the petition, alongside information readily available in our files, indicates that the petitioned entity constitutes a ''species'' eligible for listing under the ESA. Next, if we conclude the petition presents substantial scientific or commercial information suggesting that the petitioned entity may constitute a species, we evaluate whether the information indicates that the species may face an extinction risk such that listing, delisting, or reclassification may be warranted; this may be indicated in information expressly discussing the species' status and trends, or in information describing impacts and threats to the species. We evaluate whether the petition presents any information on specific demographic factors pertinent to evaluating extinction risk for the species (*e.g.,* population abundance and trends, productivity, spatial structure, age structure, sex ratio, diversity, current and historical range, habitat integrity or fragmentation), and the potential contribution of identified demographic risks to extinction risk for the species. We then evaluate whether the petition presents information suggesting potential links between these demographic risks and the causative impacts and threats identified in section 4(a)(1) of the ESA.

Information presented on impacts or threats should be specific to the species and should reasonably suggest that one or more of these factors may be operative threats that act, or have acted, on the species to the point that it may warrant protection under the ESA. Broad statements about generalized threats to the species, or identification of factors that could negatively impact a species, do not constitute substantial information indicating that listing may

be warranted. We look for information indicating that not only is the particular species exposed to a factor, but that the species may be responding in a negative fashion. We then assess the potential significance of that negative response.

Many petitions identify risk classifications made by nongovernmental organizations, such as the International Union for Conservation of Nature (IUCN), the American Fisheries Society, or NatureServe, as evidence of extinction risk for a species. Risk classifications by other organizations or made under other Federal or State statutes may be informative, but such classification alone may not provide the rationale for a positive 90-day finding under the ESA. For example, as explained by NatureServe, their assessments of a species' conservation status do ''not constitute a recommendation by NatureServe for listing under the U.S. Endangered Species Act'' because NatureServe assessments ''have different criteria, evidence requirements, purposes and taxonomic coverage than government lists of endangered and threatened species, and therefore these two types of lists should not be expected to coincide'' (*https://explorer.natureserve.org/AboutTheData/DataTypes/ConservationStatusCategories*). Additionally, species classifications under IUCN and the ESA are not equivalent; data standards, criteria used to evaluate species, and treatment of uncertainty are also not necessarily the same. Thus, when a petition cites such classifications, we will evaluate the source of information that the classification is based upon in light of the standards on extinction risk and impacts or threats discussed above.

Distribution, Habitat, and Life History

The sunflower sea star occurs throughout intertidal and subtidal coastal waters of the Northeast Pacific Ocean from the Aleutian Islands, Alaska, to at least the Southern California Bight, and is present on a wide variety of substrate types (Britton-Simmons *et al.* 2012, Gravem *et al.* 2021). Individuals may also occupy waters off the west coast of the Baja Peninsula southward to the vicinity of San Ignacio Lagoon, though data from this region are sparse (Gravem *et al.* 2021). While most abundant in waters less than 25 meters (m) deep, sunflower sea stars can be found at considerably lower densities as deep at 300 m (Gravem *et al.* 2021).

Sunflower sea stars are broadcast spawners that require close proximity to mates for successful fertilization (Morris *et al.* 1980, Lambert 2000, Lundquist and Botsford 2004, Hodin *et al.* 2021). While it is unclear whether individuals aggregate to spawn, documentation of seasonal, patchy distribution suggests this may be the case (Mauzey *et al.* 1968, Gravem *et al.* 2021). Though reproductive seasonality is largely undocumented, localized studies have documented breeding from December through June (Feder and Christiensen 1966, Morris *et al.* 1980, Gravem *et al.* 2021), and broad geographic variation linked with water temperature and other environmental factors is likely.

Fertilization of eggs is followed by a free-floating larval period of 50–146 days (Strathmann 1978, Gravem *et al.* 2021), during which considerable wind- and current-driven dispersion may occur. Individuals then settle and metamorphose into juveniles, which continue to feed and grow. Though age at first maturity remains unknown for the sunflower sea star, the well-studied ochre star *Pisaster ochraceus,* another large predatory sea star that shares habitat, diet, and reproductive strategy with the sunflower sea star, first reproduces at age 5 (Menge 1975). As is common for a broad diversity of marine species, it is also likely that sunflower sea star fecundity increases with size (Gravem *et al.* 2021). Sea star size is strongly affected by environmental factors such as temperature and food availability (Sebens 1987, Gooding *et al.* 2009), making size a poor indicator of age, but estimates suggest that maximum age could be as high as 68 years, but is more typically ~15 years in the wild (Gravem *et al.* 2021).

Status and Population Trends

There is no single, systematically collected data set that provides population size or long-term trend data for sunflower sea stars throughout their range. A recent compilation by the IUCN of localized data sets spanning from the Aleutian Islands, Alaska, to Baja California, Mexico, compared regional trends to evaluate range-wide status (Gravem *et al.* 2021; Hamilton et al. 2021). While considerable variability was apparent in many locations, since 2000 nearly all data sets considered indicate substantial regional declines in average density, with some declines exceeding 90 percent. From 2013–17, an outbreak of sea star wasting syndrome (SSWS) contributed to precipitous population declines in several areas, with impacts progressing sequentially from south to north (Gravem *et al.* 2021). Data were not collected evenly over time and space, however, making some estimates of decline less reliable than others. Additionally, most data were collected from shallow, nearshore areas such that deep-water abundance could only be estimated for the whole of the range rather than on a regional level. As noted above, most sunflower sea stars occupy waters less than 25 m deep, minimizing the relevance of this shortcoming in regionalized data collection. Bearing these caveats in mind, researchers estimated that global sunflower sea star population size declined by 90.6 percent from 2013–17 due to SSWS (Gravem *et al.* 2021), and minimal recovery has been noted since (Hamilton *et al.* 2021). Not only has population size decreased, but area of occupancy has also declined by an estimated 57.6 percent since the SSWS outbreak, and sunflower sea stars have not been detected in several surveys where they were once common components of the catch (Gravem *et al.* 2021).

In sum, while data on abundance and trends are incomplete and likely span only one generation time for the species, the information presented in the petition indicates that sunflower sea star populations have declined throughout the species' range, with especially steep declines from 2013–17.

Analysis of ESA Section 4(a)(1) Factors

The petitioners assert that *P. helianthoides* is endangered or threatened because of all five of the ESA section 4(a)(1) factors: The present or threatened destruction, modification, or curtailment of its habitat or range; overutilization for commercial, recreational, scientific, or educational purposes; disease or predation; inadequacy of existing regulatory mechanisms to address identified threats; and other natural or manmade factors affecting its continued existence, including climate change. Information in the petition and information that was readily available in our files indicate that the primary threat facing the species is disease, specifically SSWS. We briefly reiterate the evidence for each of the five factors, as presented in the petition, below.

Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

The petitioner asserts that the SSWS outbreak that occurred from 2013–17 resulted in an estimated 57.6 percent decline in area of occupancy throughout the sunflower sea star's known range (Gravem *et al.* 2021), representing substantial range curtailment. This includes evidence for local extirpation of the species in some regions, such as along the outer coasts of Washington, Oregon, California, and Mexico. The

petition also notes that shoreline armoring, coastal development, erosion, pollution, shipping, harmful algal blooms, and invasive species all represent habitat stressors in the nearshore environments preferred by sunflower sea stars. While there is substantial variation in the intensity and interactivity of these stressors across the range of the sunflower sea star, urbanized estuaries like San Francisco Bay and the Salish Sea are likely to be especially heavily impacted. Given that these urbanized areas historically contained substantial populations, the overall impact on sunflower sea stars may be substantial.

Overutilization for Commercial, Recreational, Scientific or Educational Purposes

Sunflower sea stars are not specifically targeted in any commercial fisheries, but are a component of bycatch in several pot, trap, trawl, and seine fisheries. Removing individuals from such gear may lead to injury or mortality. Recreational harvest is also permitted in Alaska, Oregon, California, and Mexico, although it is banned in Washington. Dried sunflower sea stars are also sold as curios and for home decoration. While direct loss of sunflower sea stars by these methods, in total, is believed to be low, the petition contends that even small effects could exacerbate the effects of low population size.

Disease or Predation

The petitioners assert that the species is endangered or threatened primarily because of population declines caused by SSWS. As discussed above in Status and Population Trends, SSWS has caused an estimated population decline of over 90 percent on a range-wide basis and local extirpation in some regions. The high lethality and broad-scale losses of sea stars due to SSWS may substantially impede access to mates, resulting in reduced population viability and resilience, and increasing extinction risk (Gravem *et al.* 2021).

Inadequacy of Existing Regulatory Mechanisms

The petitioner notes two broad areas in which existing regulatory mechanisms are inadequate to address threats to the species: The control/prevention of SSWS and other diseases; and the regulation of greenhouse gas emission and climate change impacts, especially warming ocean temperatures, which may exacerbate disease outbreaks. The petition notes that status reviews for other species have acknowledged that there are no effective mechanisms to regulate greenhouse gas emissions on the national or international level.

Other Natural or Manmade Factors

The petitioners assert that climate change, sea level rise, and ocean acidification all represent range-wide threats to the continued existence of the sunflower sea star, according to the petition. Sea level rise may lead to increased shoreline armoring and loss of habitat, while increased sea surface temperature can exacerbate disease outbreaks. Ocean acidification affects sunflower sea star prey viability in the Northeast Pacific Ocean, causing physiological stress for a variety of bivalves and other organisms that rely on calcium deposition to create protective shells (Bednarsek *et al.* 2021). Increased acidity also directly inhibits growth and development of larval and juvenile sea stars, as well as affecting metabolic rate, energy demand, and arm regeneration rate in adults.

Petition Finding

After reviewing the petition, the literature cited in the petition, and other information readily available in our files, we conclude the petition presents substantial scientific information indicating that the petitioned action to list *P. helianthoides* as a threatened or endangered species may be warranted. Therefore, in accordance with section 4(b)(3)(A) of the ESA and NMFS' implementing regulations (50 CFR 424.14(h)(2)), we will commence a status review to determine whether the sunflower sea star is in danger of extinction throughout all of a significant portion of its range, or likely to become so within the foreseeable future throughout all or a significant portion of its range. As required by section 4(b)(3)(B) of the ESA, within 12 months of the receipt of the petition (August 18, 2022), we will make a finding as to whether listing the sunflower sea star as an endangered or threatened species is warranted. If listing is warranted, we will publish a proposed rule and solicit public comments before developing and publishing a final rule.

Information Solicited

To ensure that the status review is based on the best available scientific and commercial data, we are soliciting comments and information from interested parties on the status of the sunflower sea star. Specifically, we are soliciting information in the following areas:

(1) Historical and current abundance and population trends of *P. helianthoides* at all available geographic scales throughout its range;

(2) Historical and current distribution and population structure of *P. helianthoides;*

(3) Historical and current condition of habitat for *P. helianthoides;*

(4) Historical and current data on bycatch and retention of *P. helianthoides* in commercial, artisanal, and recreational fisheries worldwide;

(5) Data on trade of *P. helianthoides,* including dried specimens sold as curios;

(6) Historical and current impacts of SSWS on *P. helianthoides* at all available geographic scales throughout its range;

(7) The effects of other known or potential threats to *P. helianthoides* over the short-term or long-term; and

(8) Management, regulatory, or conservation programs that may be relevant for *P. helianthoides,* including mitigation measures related to any known or potential threats to the species throughout its range.

We request that all data and information be accompanied by supporting documentation such as maps, bibliographic references, or reprints of pertinent publications. Please send any comments in accordance with the instructions provided in the **ADDRESSES** section above. We will base our findings on a review of the best available scientific and commercial information available, including all information received during the public comment period.

References Cited

A complete list of all references cited herein is available upon request (See **FOR FURTHER INFORMATION CONTACT**).

Authority: The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: December 20, 2021.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2021–27931 Filed 12–23–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 211217–0263]

RIN 0648–BK90

Pacific Island Fisheries; 2022–2025 Annual Catch Limits and Accountablility Measures for Main Hawaiian Islands Uku (Gray Jobfish)

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement an annual catch limit (ACL) of 295,419 lb (134 metric tons (t)), an annual catch target (ACT) of 291,010 lb (132 t), and accountability measures (AM) for main Hawaiian Islands (MHI) uku for fishing years 2022, 2023, 2024, and 2025. These ACLs and ACTs apply to the total combined commercial and non-commercial catch of uku. As an in-season accountability measure, if NMFS projects that the total catch will reach the ACT in any given fishing year, we would close commercial and non-commercial uku fisheries in Federal waters for the remainder of the fishing year. As a post-season AM, if NMFS determines that the most recent three-year average total catch exceeded the ACL in a fishing year, we would reduce the ACL and ACT for the following fishing year by the amount of the overage. The proposed rule supports the long-term sustainability of MHI uku.

DATES: NMFS must receive comments by January 26, 2022.

ADDRESSES: You may submit comments on the proposed rule, identified by NOAA–NMFS–2021–0088, by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter NOAA–NMFS–2021–0088 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Send written comments to Michael D. Tosatto, Regional Administrator, NMFS Pacific Islands Regional Office (PIRO), 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

The Western Pacific Fishery Management Council (Council) and NMFS prepared an environmental assessment (EA) that supports this proposed rule. The EA is available at *www.regulations.gov,* or from the Council, 1164 Bishop St., Suite 1400, Honolulu, HI 96813, tel 808–522–8220, or *www.wpcouncil.org.*

FOR FURTHER INFORMATION CONTACT: David O'Brien, NMFS PIRO Sustainable Fisheries, 808–725–5038.

SUPPLEMENTARY INFORMATION: NMFS and the Council manage the MHI uku fishery in Federal waters around Hawaii under the Fishery Ecosystem Plan for the Hawaiian Archipelago (FEP), as authorized by the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The regulations at 50 CFR 665.4 require NMFS to specify an ACL, and optionally specify an ACT, for MHI uku each fishing year based on a recommendation from the Council. The specification of an ACT reduces the likelihood that the ACL will be exceeded.

The Council, at its September 2021 meeting, recommended that NMFS implement the proposed ACLs, ACTs, and AMs for MHI uku for 2022, 2023, 2024, and 2025. The fishing year for MHI uku is the calendar year. The Council recommended the proposed ACL of 295,419 lb (134 t) and ACT of 291,010 lb (132 t) based on a 2020 MHI uku stock assessment, in consideration of the risk of overfishing, past fishery performance, the acceptable biological catch recommendation from its Scientific and Statistical Committee, and with opportunity for public input.

The 2020 stock assessment found that the MHI uku stock is healthy and estimated the overfishing limit to be 302,033 lb (137 t), assuming four years of identical catch in 2022, 2023, 2024, and 2025. This new overfishing limit is the first time the limit has been specified for total catch. Previous stock assessments and overfishing limits for MHI uku considered commercial catch only. The proposed ACLs and ACTs are associated with up to a 41 and 36 percent probability of overfishing, respectively, for each proposed fishing year. Both are more conservative than the 50 percent risk threshold allowed under NMFS guidelines for Magnuson-Stevens Act National Standard 1 requiring that fishery management measures prevent overfishing.

NMFS monitors MHI uku catches based on data provided by commercial fishermen to the State of Hawaii, and by non-commercial fishermen to the State of Hawaii and NMFS. As an in-season AM, if NMFS projects that total catch will reach the ACT, we would close Federal waters to the commercial and non-commercial fisheries for MHI uku for the remainder of the fishing year. As a post-season AM, if NMFS determines that the most recent three-year average MHI uku total catch exceeds the ACL in any given year, NMFS would reduce the ACL and ACT for the subsequent fishing year by the amount of the overage with a subsequent rulemaking.

The combined commercial and non-commercial fishery has only caught more than the proposed ACT one year in the past 11 years (2012), suggesting there is a roughly one in three chance the fishery will reach the ACT in one or more years specified in this proposed rule. If the fishery was to reach the ACT requiring closure of Federal waters, we expect it would be late in the year and have minor impacts to the fishery. We do not anticipate changes to the fishery that would result in significant environmental impacts.

NMFS will consider public comments on this proposed rule and will announce the final rule in the **Federal Register**. NMFS must receive any comments by the date provided in the **DATES** heading, not postmarked or otherwise transmitted by that date. Regardless of the final rule, all other management measures will continue to apply in the fisheries.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the FEP, other provisions of the Magnuson-Stevens Act, and other applicable laws, subject to further consideration after public comment.

Certification of Finding of No Significant Impact on Substantial Number of Small Entities

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that the attached proposed rule, issued under the authority of the Magnuson-Stevens Act, will not have a significant

economic impact on a substantial number of small entities.

The proposed action would implement an ACL of 295,419 lb (134 t), an ACT of 291,010 lb (132 t), and both in-season and post-season AM for uku in the U.S. Exclusive Economic Zone around the MHI for fishing years 2022, 2023, 2024, and 2025.

Uku caught by commercial and non-commercial fishermen would all count toward the ACL and ACT under this action. This would include catch by anyone who is required to report catch to State or Federal agencies. As a result, this action would apply to hundreds of small entities across Hawaii who would potentially participate in the MHI uku fishery. On average over the last five years, commercial fishermen reported 92,902 lb (42.1 t) of uku caught, and sold 85,641 lb (38.8 t) (92.2 percent) for $412,790. Based on information collected by the State of Hawaii and NMFS, the five-year annual average of commercial and non-commercial uku catch was 218,874 lb (99.3 t). NMFS estimates that all participants in this fishery are small entities.

NMFS and the Council will monitor commercial and non-commercial uku catches relative to the ACL and ACT. As an in-season AM, NMFS will close Federal waters to uku retention in any fishery when we project combined commercial and non-commercial catches will reach the ACT. As a post-season AM, if NMFS determines that the average combined commercial and non-commercial catch estimates from the most recent three years exceeded the ACL, we would reduce the ACL and ACT for the following year by an amount equal to the overage.

NMFS implemented an ACL of 127,205 lb (57.7 t) for MHI uku as a single species stock starting in 2019, 2020, and 2021, which only applied to catch in the commercial fishery. The Council recommended that non-commercial catch estimates be incorporated into uku management beginning in 2022. In the 11 years from 2010 through 2020, the combined total catch of uku in commercial and non-commercial fisheries exceeded the proposed 2022–2025 ACT and ACL only once (in 2012) when total uku catch was 323,182 lb (147 t). At no point during 2010–2020 did the three-year combined average uku catch reach the proposed ACL. The most recent three years of combined commercial and non-commercial uku catches were 238,272 lb (108 t), 228,562 lb (104 t), and 218,254 lb (100 t) in 2018, 2019, and 2020, respectively.

Given the catch history, there is roughly a one in three chance that the combined total fishery catch will reach the ACT at least once during the 2022–2025 period, which would result in an in-season closure in Federal waters. If NMFS projects the ACT to be reached in a given year, we would close Federal waters to uku retention through a **Federal Register** notice. In the event that NMFS needs to reduce an ACL and ACT because the fishery three-year average catch exceeded the ACL, we would also implement the modified ACL and ACT through a **Federal Register** notice. If the fishery is projected to reach the ACT resulting in an in-season closure of Federal waters, we anticipate that it would occur near the end of the year. Fishermen could continue to fish for other species in Federal waters and for uku—both commercially and non-commercially—in State waters. All uku caught in State waters after a closure in Federal waters would still count toward the total catch for that year relative to the post-season AM.

The lack of a concurrent uku fishery closure in State waters may make enforcement of the Federal waters closure more difficult because, without an enforcement officer observing the catch locations, it would be impossible to know if an uku was caught in Federal or State waters. Even so, NMFS has utilized an in-season closure as an AM in the Hawaii Deep 7 bottomfish fishery since 2007, and enforced its closure when the fishery reached its catch limit in each of 2007–2010. Under all alternatives, if the MHI uku fishery were closed in Federal waters, the NOAA Office of Law Enforcement and the U.S. Coast Guard would be responsible for enforcing the closure. The boundary between State and Federal waters is easily determined using the Global Positioning System.

Regardless, the combination of total uku catch history, past level of uku catch in Federal waters, any closure likely occurring at the end of the season, and any uku catch after a Federal closure being counted toward the ACL, indicates that limitations on enforcement of the Federal closure will have limited negative effects on the management of the fishery. For the same reasons, even though this proposed action would apply to a substantial number of vessels, it should not result in significant adverse economic impact to individual vessels.

For Regulatory Flexibility Act (RFA) purposes only, NMFS has established a small business size standard, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide. Based on available information, NMFS has determined that all affected entities are small entities, *i.e.,* they are engaged in the business of fish harvesting, are independently owned or operated, are not dominant in their field of operation, and have gross receipts not in excess of $11 million. Therefore, there would be no disproportionate economic impacts between large and small entities. Furthermore, there would be no disproportionate economic impacts among the universe of vessels based on gear, home port, or vessel length.

For most of the fisheries subject to this proposed action, fishermen would be able to fish throughout the entire year. The ACLs, as proposed, would not change the gear type, areas fished, effort, or participation of the fisheries during the fishing years under consideration. The proposed action does not duplicate, overlap, or conflict with other Federal rules and is not expected to have significant impact on small entities (as discussed above), organizations, or government jurisdictions. The proposed action also will not place a substantial number of small entities, or any segment of small entities, at a significant competitive disadvantage to large entities.

For the reasons above, NMFS does not expect the proposed action to have a significant economic impact on a substantial number of small entities. As a result, an initial regulatory flexibility analysis is not required and none has been prepared.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

This proposed rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 50 CFR Part 665

Accountability measures, Annual catch limits, Bottomfish, Fisheries, Fishing, Hawaii, Pacific Islands.

Dated: December 17, 2021.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS proposes to amend 50 CFR part 665 as follows:

PART 665—FISHERIES IN THE WESTERN PACIFIC

■ 1. The authority citation for 50 CFR part 665 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 665.211, revise the section heading and paragraphs (a) and (b), redesignate paragraph (e) as paragraph (f), and add a new paragraph (e).

The revisions and addition read as follows:

§ 665.211 Annual Catch Limits (ACL) and Annual Catch Targets (ACT).

(a) In accordance with § 665.4, the ACLs and ACTs for MHI bottomfish fisheries for each fishing year are as follows:

Fishery	2018–19 ACL (lb)	2019–20 ACL (lb)	2020–21 ACL (lb)
Deep 7 bottomfish	492,000	492,000	492,000

Fishery	2022 ACL (lb)	2023 ACL (lb)	2024 ACL (lb)	2025 ACL (lb)
Uku	295,419	295,419	295,419	295,419

Fishery	2022 ACT (lb)	2023 ACT (lb)	2024 ACT (lb)	2025 ACT (lb)
Uku	291,010	291,010	291,010	291,010

(b) When a bottomfish ACL or ACT is projected to be reached based on analyses of available information, the Regional Administrator shall publish a document to that effect in the **Federal Register** and shall use other means to notify permit holders. The document will include an advisement that the fishery will be closed beginning at a specified date, which is not earlier than seven days after the date of filing the closure notice for public inspection at the Office of the Federal Register, until the end of the fishing year in which the ACL or ACT is reached.

* * * * *

(e) If the average total landings of uku in the most recent three years exceed the specified ACL in a fishing year, the Regional Administrator will reduce the uku ACL and ACT for the subsequent year by the amount of the overage in a separate rulemaking.

* * * * *

[FR Doc. 2021–27794 Filed 12–23–21; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 86, No. 245
Monday, December 27, 2021

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

[Document Number AMS–SC–21–0100]

Virtual Meeting of the Fruit and Vegetable Industry Advisory Committee

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the Agricultural Marketing Service (AMS), U.S. Department of Agriculture (USDA), is announcing a meeting of the Fruit and Vegetable Industry Advisory Committee (FVIAC). The meeting is being convened to examine industry recommendations provided by the Produce Marketing Association (PMA) and the United Fresh Produce Association (United Fresh). During the two-day FVIAC public meeting held November 3–4, 2021, the industry trade groups jointly submitted recommendations for discussion and consideration by FVIAC representatives. This virtual meeting will provide FVIAC representatives the opportunity to engage with United Fresh-PMA stakeholders.

DATES: The FVIAC will meet via webinar (virtually) on February 01, 2022, from 10:00 a.m. to 3:00 p.m. Eastern Time (ET). The deadline to submit written comments is 11:59 p.m. ET, on January 26, 2022.

ADDRESSES: The webinar for the meeting and public comment period can be accessed via the internet and/or phone. Members of the public must register in advance for this webinar: *https://www.zoomgov.com/webinar/register/WN_97rK0ODLS7ev7SGFYwzEMw.* Access information will also be available on the AMS website prior to the event. Detailed information can be found at *https://www.ams.usda.gov/about-ams/facas-advisory-councils/fviac.*

FOR FURTHER INFORMATION CONTACT: Darrell Hughes, Designated Federal Officer, Fruit and Vegetable Industry Advisory Committee, USDA—AMS-Specialty Crops Program, 1400 Independence Avenue SW, Suite 1575, STOP 0235, Washington, DC 20250–0235; Telephone: (202) 378–2576; Email: *SCPFVIAC@usda.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2), the Secretary of Agriculture (Secretary) established the Committee in 2001 to examine the full spectrum of issues faced by the fruit and vegetable industry and to provide suggestions and ideas to the Secretary on how USDA can tailor its programs to meet the fruit and vegetable industry's needs.

The AMS Deputy Administrator for the Specialty Crops Program serves as the Committee's Executive Secretary, leading the effort to administer the Committee's activities. Representatives from USDA mission areas and other government agencies affecting the fruit and vegetable industry are periodically called upon to participate in the Committee's meetings as determined by the Committee. AMS is giving notice of the Committee meeting to the public so that they may participate and present their views via written comments. The meeting is open to the public.

Agenda items may include, but are not limited to, welcome and introductions; administrative matters; consideration of recommendations pertaining to labor and production, food safety, climate and infrastructure, and consumption; and presentations by subject matter experts as requested by the Committee.

Written Comments: Written public comments will be accepted on or before 11:59 p.m. ET on January 26, 2022 via *http://www.regulations.gov:* Document # AMS–SC–21–0100. Comments submitted after this date will be provided to AMS, but the Committee may not have adequate time to consider those comments prior to the meeting. AMS, Specialty Crops Program, strongly prefers that comments be submitted electronically. However, written comments may also be submitted (*i.e.,* postmarked) via mail to the person listed in the **FOR FURTHER INFORMATION CONTACT** section by or before the deadline.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpretation, assistive listening devices, or other reasonable accommodation, to the person listed under the **FOR FURTHER INFORMATION CONTACT** section. Determinations for reasonable accommodation will be made on a case-by-case basis.

Dated: December 21, 2021.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2021–28008 Filed 12–23–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2020–0106]

Importation of Pummelo From Vietnam Into the United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that we have prepared a pest risk analysis that evaluates the risks associated with importation of fresh pummelo fruit from Vietnam into the United States. Based on the analysis, we have determined that the application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of fresh pummelo fruit from Vietnam. We are making the pest risk analysis available to the public for review and comment.

DATES: We will consider all comments that we receive on or before February 25, 2022.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* Enter APHIS–2020–0106 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2020–0106, Regulatory Analysis

and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *www.regulations.gov* or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Sam Johnson, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1231; (301) 442–6583.

SUPPLEMENTARY INFORMATION:

Background

Under the regulations in ''Subpart L—Fruits and Vegetables'' (7 CFR 319.56–1 through 319.56–12, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into or disseminated within the United States.

Section 319.56–4 contains a performance-based process for approving the importation of fruits and vegetables that, based on the findings of a pest risk analysis, can be safely imported subject to one or more of the five designated phytosanitary measures listed in paragraph (b) of that section.

APHIS received a request from the national plant protection organization of Vietnam to allow the importation of fresh pummelo fruit (*Citrus maxima* Merrill) from Vietnam into the United States. As part of our evaluation of Vietnam's request, we have prepared a pest risk assessment (PRA) to identify the pests of quarantine significance that could follow the pathway of the importation of fresh pummelo fruit into the United States from Vietnam. Based on the PRA, a risk management document (RMD) was prepared to identify phytosanitary measures that could be applied to the fresh pummelo fruit to mitigate the pest risk.

Therefore, in accordance with § 319.56–4(c), we are announcing the availability of our PRA and RMD for public review and comment. Those documents, as well as a description of the economic considerations associated with the importation of fresh pummelo fruit from Vietnam, may be viewed on the *Regulations.gov* website or in our reading room (see **ADDRESSES** above for a link to *Regulations.gov* and information on the location and hours of the reading room). You may request paper copies of the PRA and RMD by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the subject of the analysis you wish to review when requesting copies.

After reviewing any comments we receive, we will announce our decision regarding the import status of fresh pummelo fruit from Vietnam in a subsequent notice. If the overall conclusions of our analysis and the Administrator's determination of risk remain unchanged following our consideration of the comments, then we will authorize the importation of fresh pummelo fruit from Vietnam into the United States subject to the requirements specified in the RMD.

Authority: 7 U.S.C. 1633, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 20th day of December 2021.

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2021–27928 Filed 12–23–21; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2020–0071]

Classify Canada as Level I for Bovine Tuberculosis and Brucellosis

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our decision to classify Canada as Level I for both bovine tuberculosis and brucellosis. This recognition is based on evaluations we prepared in connection with this action, which we made available to the public for review and comment through a previous notice.

DATES: Imports under this classification may be authorized beginning December 27, 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Kelly Rhodes, Senior Staff Veterinarian, Regionalization Evaluation Services, Strategy and Policy, VS, APHIS, USDA, 4700 River Road Unit 38, Riverdale, MD 20737–1231; *Ask.Regionalization@usda.gov*; (301) 851–3315.

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 93, subpart D (§§ 93.400 through 93.442, referred to below as part 93 or the subpart), contain requirements for the importation of ruminants into the United States to address the risk of introducing or disseminating diseases of livestock within the United States. Part 93 currently contains provisions that address the risk that imported bovines (cattle or bison) may introduce or disseminate bovine tuberculosis or brucellosis within the United States. Within part 93, § 93.437 contains the requirements for classification of foreign regions for bovine tuberculosis and § 93.438 contains the process for requesting regional classification for bovine tuberculosis. In accordance with § 93.437(f), the Animal and Plant Health Inspection Service (APHIS) maintains lists of all Level I, Level II, Level III, Level IV, and Level V regions for bovine tuberculosis and adds foreign regions classified in accordance with § 93.438 to these lists.

Section 93.440 contains the requirements for classification of foreign regions for brucellosis and § 93.441 contains the process for requesting regional classification for brucellosis. In accordance with § 93.440(d), APHIS maintains lists of all Level I, Level II, and Level III regions for brucellosis and adds regions classified in accordance with § 93.441 to these lists.

Paragraph (a) of § 93.438 provides that a representative of a national government with authority to make such a request may request that APHIS classify a region for bovine tuberculosis; paragraph (a) of § 93.441 has a similar provision with respect to requests for brucellosis classification. Within those same sections, paragraph (b) provides that if, after reviewing and evaluating the request for bovine tuberculosis or brucellosis classification, respectively, APHIS believes the region can be accurately classified, APHIS will publish a notice in the **Federal Register** with the proposed classification and make its evaluation available for public comment. Following the close of the comment period, APHIS will review all comments received and will make a final determination regarding the request that will be detailed in another document published in the **Federal Register**.

In accordance with that process, we published a notice [1] in the **Federal Register** on February 24, 2021 (86 FR

[1] To view the notice, evaluations, environmental assessment, and comment we received, go to *www.regulations.gov* and enter APHIS–2020–0071 in the Search field.

11218–11219, Docket No. APHIS–2020–0071), in which we announced the availability, for review and comment, of evaluations of Canada for bovine tuberculosis and brucellosis classification, as well as an environmental assessment (EA). The notice proposed to classify Canada as Level I for both bovine tuberculosis and brucellosis.

We solicited comments on the notice for 60 days ending April 26, 2021. We received one comment by that date. The comment was from a private citizen.

The commenter stated that it was difficult to know what the different classification levels for disease status meant and asked that we explain what they meant.

As we explained in the notice, § 93.437 of the regulations contains the requirements for classification of foreign regions for bovine tuberculosis and § 93.438 contains the process for requesting regional classification for bovine tuberculosis. As part of the process for requesting regional classification, the national government of the region must submit an application to APHIS that defines the boundaries of the region, specifies the prevalence level for bovine tuberculosis within the region, and demonstrates that, among other things:

- There is effective veterinary control and oversight within the region;
- Bovine tuberculosis is a notifiable disease within the region; and
- The region has a program for bovine tuberculosis in place that includes epidemiological investigations, management of affected herds, diagnostic testing, and disease surveillance.

The specific requirements for classification as a Level I region for bovine tuberculosis are set out in paragraph (a) of § 93.437. To receive Level I classification for bovine tuberculosis, a region must meet APHIS requirements for bovine tuberculosis classification in accordance with § 93.438, and a prevalence of tuberculosis in their domestic bovine herds of less than 0.001 percent over at least the previous 2 years (24 consecutive months).

In the evaluation titled ''APHIS Evaluation of Canada for Bovine Tuberculosis (*Mycobacterium bovis*) Classification'' (April 2020) that accompanied our February 24, 2021 notice,[2] we set forth the results of our evaluation of Canada for bovine tuberculosis. APHIS found that Canada fully meets APHIS requirements for classification and that the prevalence of bovine tuberculosis in Canada appears to be well below 0.001 percent, meaning that Canada qualifies for classification as Level I. The evaluation also noted that such classification effectively exempts all Canadian cattle and bison exported to the United States from bovine tuberculosis testing prior to export.

Similarly, as we explained in the notice, § 93.440 of the regulations contains the requirements for classification of foreign regions for brucellosis and § 93.441 contains the process for requesting regional classification for brucellosis. The process for requesting regional brucellosis classification is similar to the process for requesting regional bovine tuberculosis classification summarized above.

The specific requirements for classification as a Level I region for brucellosis are set out in paragraph (a) of § 93.440. To receive Level I classification for brucellosis, a region must meet APHIS requirements for brucellosis classification in accordance with § 93.441, and also have a prevalence of brucellosis in their domestic bovine herds of less than 0.001 percent over at least the previous 2 years (24 consecutive months).

In the evaluation titled ''APHIS Evaluation of Canada for Bovine Brucellosis (*Brucella abortus*) Classification'' (May 2020) that accompanied our February 24, 2021 notice,[3] we set forth the results of our evaluation of Canada for bovine brucellosis. APHIS found that Canada fully meets the APHIS requirements for classification and that brucellosis has not been confirmed in a bovine animal in that country since 1989, qualifying Canada for Level I classification for brucellosis. The evaluation also noted that such classification effectively exempts all Canadian cattle and bison exported to the United States from brucellosis testing.

Therefore, in accordance with the regulations in §§ 93.437 and 93.440, we are announcing our decision to classify Canada as Level I for both bovine tuberculosis and brucellosis, and to add Canada to the web-based list of Level I regions for bovine tuberculosis and the web-based list of Level I regions for brucellosis. Bovines from Canada may be imported under the conditions listed in §§ 93.439 and 93.442 for the appropriate classification level.

National Environmental Policy Act

After reviewing and evaluating the comment received during the comment period on the draft EA, evaluations, and other information, APHIS has prepared a final EA, which provides the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the classification of Canada as Level I for bovine tuberculosis and brucellosis. The EA was prepared in accordance with: (1) The National Environmental Policy Act (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). Based on our EA, the response to public comment, and other pertinent information, APHIS has reached a finding of no significant impact (FONSI) with regard to the classification of Canada as Level I for bovine tuberculosis and brucellosis.

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 action as not a major rule, as defined by 5 U.S.C. 804(2).

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4

Done in Washington, DC, this 21st day of December 2021.

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2021–28057 Filed 12–23–21; 8:45 am]

BILLING CODE 3410–34–P

[2] See footnote 1.

[3] See footnote 1.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2021–0073]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Cooperative State-Federal Brucellosis Eradication Program

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection

associated with the Cooperative State-Federal Brucellosis Eradication Program.

DATES: We will consider all comments that we receive on or before February 25, 2022.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* Enter APHIS–2021–0073 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2021–0073, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *regulations.gov* or in our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the Cooperative State-Federal Brucellosis Eradication Program, contact Dr. P. Ryan Clarke, Senior Staff Veterinarian, Ruminant Health Center, Strategy and Policy, Veterinary Services, APHIS, Bozeman, MT; (406) 539–6899; *patrick.r.clarke@usda.gov.* For more information on the information collection reporting process, contact Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851–2483; *joseph.moxey@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Cooperative State-Federal Brucellosis Eradication Program.

OMB Control Number: 0579–0047.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: The Animal Health Protection Act (7 U.S.C. 8301 *et seq.*) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any animal or related material if necessary, to prevent the spread of any livestock or poultry pest or disease.

Disease prevention and disease surveillance are the most effective methods for maintaining a healthy animal population and for enhancing the United States' ability to compete in the world market of animal and animal product trade. Veterinary Services (VS) within the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) is responsible for administering regulations intended to protect the health of the U.S. livestock population.

Brucellosis is an infectious disease of animals and humans caused by bacteria of the genus *Brucella.* The disease is characterized by abortions and impaired fertility in its principal animal hosts. The disease infects humans through contact with infected animals or with certain body fluids of infected animals. Usually *Brucella abortus* is associated with the disease in cattle or bison, *Brucella suis* with the disease in swine, and *Brucella melitensis* with the disease in sheep and goats. The continued presence of brucellosis in a herd seriously threatens the health, welfare, and economic viability of the livestock industry. There is no economically feasible treatment for brucellosis in livestock.

The Cooperative State-Federal Brucellosis Eradication Program is a national program to eliminate this serious disease of livestock. The program is conducted under the authority of the various States and supplemented by Federal authorities regulating interstate movement of infected animals. Regulations in 9 CFR part 78 outline the Cooperative State-Federal Brucellosis Eradication Program. The regulations include required surveillance, epidemiological investigation, annual reporting, and interstate movement activities that must be documented.

Minimum program standards known as the Brucellosis Eradication Uniform Methods and Rules (UM&R) have been developed cooperatively by organizations representing the livestock industry, State animal health agencies, and the USDA. State and Federal officials in charge of program activities in each State are responsible for continuously evaluating the efficiency of local procedures in locating and eliminating infected livestock. The minimum standards in the UM&R must be met or exceeded throughout the certification period to maintain continuous status. Meeting these standards requires information collection.

Information is generally collected by State and Federal animal health officials through interviews or reviewing records. In addition, the information on some documents may be collected by private veterinary practitioners (*i.e.,* test charts, vaccination records, and official Certificates of Veterinary Inspection) or blood collection personnel on contract (*i.e.,* market cattle slaughter surveillance blood collection forms and brucellosis ring testing milk sample collection forms). The information is collected at the time each appropriate event occurs. In most instances, information is collected when testing or vaccinating individual animals or herds, applying official identification to animals, or conducting surveillance or epidemiological investigation activities. Some events, such as market cattle slaughter surveillance, occur daily. Other events, such as on-farm blood testing and vaccination, occur as part of routine animal health management. A few events, such as infected-herd investigations, occur only a few times a year.

In addition, the bovine brucellosis program regulations in part 78 provide a system for classifying States or portions of States according to the rate of *B. abortus* infection present and the general effectiveness of a brucellosis control and eradication program. The program also provides for the creation of brucellosis management areas within a State and for testing and movement mitigation activities before regulated animals are permitted to move interstate. This system enhances the ability of States to move healthy, brucellosis-free cattle and bison interstate and internationally. This management area and testing system also enhances the effectiveness of the Brucellosis Eradication Program by decreasing the likelihood that infected animals will be moved interstate or internationally.

The creation of brucellosis management areas allows States that have found *B. abortus* in wildlife (which are nonregulated animals) to mitigate the risk of transmission and spread of disease while maintaining the State's disease-free status in regulated domestic livestock. The State must sign a memorandum of understanding with the APHIS Administrator that describes its brucellosis management plan. The brucellosis management plan developed by the State must define the geographic brucellosis management area and describe the surveillance and mitigation activities that the State will conduct to identify occurrence of *B. abortus* in domestic livestock and wildlife and potential risks for spread of the disease.

We are asking Office of Management and Budget (OMB) to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 0.26 hours per response.

Respondents: Commercial livestock farm owners and managers; animal agriculture-related business owners and managers; private veterinarians; animal agriculture-related agencies and organizations; breed registry agencies; agriculture extension agents; fair and exhibition officials; owners, operators, and managers of livestock markets; owners, operators, and managers of slaughter establishments and dairy plants; and State animal health officials and laboratory personnel (including wildlife biologists).

Estimated annual number of respondents: 21,568.

Estimated annual number of responses per respondent: 44.

Estimated annual number of responses: 957,102.

Estimated total annual burden on respondents: 247,325 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 21st day of December 2021.

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2021–28018 Filed 12–23–21; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–863]

Forged Steel Fittings From Taiwan: Final Results of Antidumping Duty Administrative Review; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that Both-Well Steel Fittings Co., Ltd (Bothwell) made sales of subject merchandise in the United States at prices below normal value during the period of review (POR), September 1, 2019, through August 31, 2020.

DATES: Applicable December 27, 2021.

FOR FURTHER INFORMATION CONTACT: George Ayache or Samuel Glickstein, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2623 or (202) 482–5307, respectively.

SUPPLEMENTARY INFORMATION:

Background

On August 30, 2021, Commerce published the preliminary results of the 2019–2020 administrative review of the antidumping duty order on forged steel fittings from Taiwan.[1] This review covers one producer/exporter of the subject merchandise, Bothwell. For the events that occurred since Commerce published the *Preliminary Results*, as well as a full discussion of the issues raised by parties for these final results, *see* the Issues and Decision Memorandum.[2] Commerce conducted this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [3]

The products covered by this *Order* are forged steel fittings from Taiwan. A full description of the scope of the *Order* is contained in the Issues and Decision Memorandum.

Analysis of Comments Received

In the Issues and Decision Memorandum, we address the sole issue raised in the case and rebuttal briefs submitted by interested parties as reflected in the list of topics provided in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade/gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on the comments received from interested parties and record information, we made no changes to our preliminary weighted-average dumping margin calculations for Bothwell.

Final Results of the Administrative Review

We determine that the following weighted-average dumping margin exists for Bothwell for the period September 1, 2019, through August 31, 2020:

Exporter/producer	Weighted-average dumping margin (percent)
Both-Well Steel Fittings Co., Ltd	5.57

Disclosure

Normally, Commerce will disclose to the parties in a proceeding the calculations performed in connection with the final results of review in accordance with 19 CFR 351.224(b). However, because Commerce made no adjustments to the margin calculation methodology used in the *Preliminary Results,* there are no calculations to disclose for the final results of review.

Assessment Rates

Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.[4] Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a

[1] *See Forged Steel Fittings from Taiwan: Preliminary Results of Antidumping Duty Administrative Review; 2019–2020,* 86 FR 48401 (August 30, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the 2019–2020 Antidumping Duty Administrative Review of Forged Steel Fittings from Taiwan,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See Forged Steel Fittings from Taiwan: Antidumping Duty Order,* 83 FR 48280 (September 24, 2018) (*Order*).

[4] *See* 19 CFR 351.212(b).

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).

Pursuant to 19 CFR 351.212(b)(1), because the respondent did not report entered value, we calculated importer-specific per-unit duty assessment rates based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total quantity of those sales. Where either the respondent's weighted-average dumping margin is zero or *de minimis* (*i.e.,* less than 0.5 percent) within the meaning of 19 CFR 351.106(c)(1), or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[5] To determine whether an importer-specific per-unit duty assessment rate is *de minimis,* we calculated an estimated entered value.

The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[6]

Consistent with Commerce's clarification of its assessment practice, for entries of subject merchandise during the POR produced by Bothwell for which it did not know the merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[7]

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of forged steel fittings from Taiwan entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results as provided by section 751(a)(2) of the Act: (1) The cash deposit rate for Bothwell will be equal to the weighted-average dumping margin established in the final results of this review; (2) for merchandise exported by producers or exporters not covered in this review but covered in a prior completed segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published in the completed segment for the most recent period; (3) if the exporter is not a firm covered in this review or the original less-than-fair-value (LTFV) investigation, but the producer is, then the cash deposit rate will be the rate established in the completed segment for the most recent period for the producer of the merchandise; (4) the cash deposit rate for all other producers or exporters will continue to be 116.17 percent, the all-others rate established in the LTFV investigation.[8] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final 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 this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation subject to sanction.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: December 20, 2021.

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—List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2021–28070 Filed 12–23–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–979]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, From the People's Republic of China: Notice of Court Decision Not in Harmony With the Results of Antidumping Duty Administrative Review; Notice of Amended Final Results

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On December 8, 2021, the U.S. Court of International Trade (CIT) issued its final judgment in *Canadian Solar International Limited et al.* v. *United States,* Consol. Court No. 17–00173, sustaining the Department of Commerce (Commerce)'s fourth remand results pertaining to the administrative review of the antidumping duty (AD) order on crystalline silicon photovoltaic cells, whether or not assembled into modules (solar cells), from the People's Republic of China (China) covering the period December 1, 2014, through November 30, 2015. Commerce is notifying the public that the CIT's final judgment is not in harmony with the final results of the 2014–2015 AD administrative review of solar cells from China and that Commerce is amending those final results with respect to the dumping margin assigned to the following companies: (1) The collapsed entity comprising Canadian Solar International Limited; Canadian Solar Manufacturing (Changshu), Inc.; Canadian Solar Manufacturing (Luoyang), Inc.; CSI Cells Co., Ltd.; CSI–GCL Solar Manufacturing (YanCheng) Co., Ltd.; and CSI Solar Power (China) Inc. (collectively, Canadian Solar); (2) the collapsed entity comprising Yingli

[5] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101, 8102 (February 14, 2012).

[6] *See* section 751(a)(2)(C) of the Act.

[7] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[8] *See Order,* 83 FR at 48281.

Energy (China) Company Limited; Baoding Tianwei Yingli New Energy Resources Co., Ltd.; Tianjin Yingli New Energy Resources Co., Ltd.; Hengshui Yingli New Energy Resources Co., Ltd.; Lixian Yingli New Energy Resources Co., Ltd.; Baoding Jiasheng Photovoltaic Technology Co., Ltd.; Beijing Tianneng Yingli New Energy Resources Co., Ltd.; Hainan Yingli New Energy Resources Co., Ltd.; and Shenzhen Yingli New Energy Resources Co., Ltd. (collectively, Yingli); and (3) Shanghai BYD Co., Ltd.

DATES: Applicable December 18, 2021.

FOR FURTHER INFORMATION CONTACT: Jeff Pedersen, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2769.

SUPPLEMENTARY INFORMATION:

Background

On June 27, 2017, Commerce published the final results of the 2014–2015 AD administrative review of solar cells from China. In the *Final Results,* Commerce selected Thailand as the primary surrogate country and relied on Thai import data to value nitrogen that was used in manufacturing solar cells.[1]

After correcting a ministerial error in the *Final Results* (*i.e.,* Commerce inadvertently omitted certain U.S. indirect selling expenses from its calculations), on August 25, 2017, Commerce published the *Amended Final Results*.[2]

Respondents, Canadian Solar, Trina,[3] Shanghai BYD Co., Ltd., and Ningbo Qixin Solar Electrical Appliance Co., Ltd. (Ningbo Qixin), and domestic interested party, SolarWorld Americas, Inc., challenged Commerce's *Amended Final Results* (CIT case numbers 17–00173, 17–00187, 17–00193, and 17–00200). Yingli sought to intervene in CIT case number 17–00197. The CIT consolidated case numbers 17–00173, 17–00187, 17–00193, 17–00197, and 17–00200 into case number 17–00173 in September 2017. On April 16, 2019, the CIT sustained Commerce's *Amended Final Results* with respect to: (1) The surrogates that it selected to value aluminum frames, nitrogen, polysilicon ingots and blocks, and financial ratios; (2) its decision to include import values with zero import quantities in its surrogate value calculations; and (3) its decision to deny Trina an offset for debt restructuring income. However, the CIT remanded the *Amended Final Results* to Commerce to reconsider, or further explain: (1) The surrogate that it selected to value solar module glass; (2) its application of an adverse inference in selecting partial facts available for use in calculating Canadian Solar's dumping margin; and (3) its decision to reject Ningbo Qixin's separate rate application.[4]

In its first remand redetermination, issued in July 2019, Commerce: (1) Under respectful protest, valued solar module glass using Bulgarian import data, rather than Thai import data; (2) further explained its determination to rely on facts available with an adverse inference in calculating Canadian Solar's dumping margin; and (3) continued to deny Ningbo Qixin a separate rate after reopening the record to permit Ningbo Qixin to establish that it made a shipment of subject merchandise to the United States during the POR (which it failed to establish).[5] The CIT sustained Commerce's redetermination with respect to the value of solar module glass, and its denial of Ningbo Qixin's request for a separate rate, but remanded to Commerce its partial adverse facts available determination with respect to Canadian Solar for a second time.[6]

In its second remand redetermination, issued in February 2020, Commerce reexamined its partial adverse facts available determination with respect to Canadian Solar and, under respectful protest, determined not to apply an adverse inference when selecting from among the facts available in calculating a dumping margin for Canadian Solar.[7] The CIT sustained Commerce's second redetermination.[8]

In June 2020, in *SolarWorld,* the U.S. Court of Appeals for the Federal Circuit (CAFC) vacated the CIT's judgement sustaining Commerce's use of Thai import data to value nitrogen in the 2013–2014 AD administrative review of solar cells from China and remanded the case for further proceedings consistent with the Court's opinion.[9] Subsequently, the CIT held that *SolarWorld* constitutes an intervening change in controlling law, and thus, it vacated its earlier judgment sustaining Commerce's valuation of nitrogen in the 2014–2015 AD administrative review of solar cells from China.[10] The CIT also remanded the nitrogen issue in the 2014–2015 AD administrative review of solar cells from China to Commerce for it to adequately explain why the Thai surrogate value for nitrogen was not aberrational or adopt an alternative surrogate value for nitrogen.

In its third remand redetermination, issued in January 2021, Commerce continued to value nitrogen using Thai import data. Specifically, in its third remand redetermination Commerce explained why it did not find the average unit value (AUV) of Thai imports of nitrogen during the period of review (POR) to be aberrational, clarified its practice for evaluating whether an AUV from a surrogate country is aberrational, and addressed the discrepancies between U.S. POR exports of nitrogen to Thailand and Thai POR imports of nitrogen from the United States.[11] The CIT remanded the case to Commerce for a fourth time, ordering Commerce to reconsider, or further explain, its use of Thai import data to value nitrogen.[12]

In its final remand redetermination, issued in September 2021, under respectful protest, Commerce used Mexican import data, rather than Thai import data, to value nitrogen.[13] The CIT sustained Commerce's final redetermination.[14]

---

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2014–2015,* 82 FR 29033 (June 27, 2017) (*Final Results*), and accompanying Issues and Decision Memorandum at Comment 13.

[2] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Amended Final Results of Antidumping Duty Administrative Review; 2014–2015,* 82 FR 40560 (August 25, 2017) (*Amended Final Results*).

[3] We used ''Trina'' to refer to the following companies that we treated as a single entity: Changzhou Trina Solar Energy Co., Ltd.; Trina Solar (Changzhou) Science and Technology Co., Ltd.; Yancheng Trina Solar Energy Technology Co., Ltd.; Changzhou Trina Solar Yabang Energy Co., Ltd.; Turpan Trina Solar Energy Co., Ltd.; and Hubei Trina Solar Energy Co., Ltd.

[4] *See Canadian Solar Int'l Ltd. et al.* v. *United States,* 378 F. Supp. 3d 1292 (CIT 2019).

[5] *See* Results of Remand Redetermination, *Canadian Solar International Limited, et al.* v. *United States,* Court No. 17–00173, Slip Op. 19–47 (Court of International Trade April 16, 2019), dated July 15, 2019.

[6] *See Canadian Solar Int'l Ltd. et al.* v. *United States,* 415 F. Supp. 3d 1326 (CIT 2019).

[7] *See Canadian Solar International Limited, et al.* v. *United States,* Court No. 17–00173, Slip Op. 19–152 (Court of International Trade December 3, 2019) Final Results of Second Redetermination Pursuant to Court Order, dated February 10, 2020.

[8] *See Canadian Solar Int'l Ltd. et al.* v. *United States,* 448 F. Supp. 3d 1333 (CIT 2020).

[9] *See SolarWorld Americas, Inc. et al.* v. *United States,* 962 F.3d 1351 (Fed. Cir. 2020) (*SolarWorld*).

[10] *See Canadian Solar Int'l Ltd. et al.* v. *United States,* 471 F. Supp. 3d 1379 (CIT 2020).

[11] *See Canadian Solar International Limited, et al.* v. *United States,* Court No. 17–00173, Slip Op. 20–134 (CIT September 14, 2020), dated January 12, 2021.

[12] *See Canadian Solar Int'l Limited et al.* v. *United States,* 532 F. Supp. 3d 1273 (CIT 2021).

[13] *See Canadian Solar International Limited, et al.* v. *United States,* Consol. Court No. 17–00173 (CIT July 28, 2021), dated September 27, 2021.

[14] *See Canadian Solar International Limited et al.* v. *United States,* Consol. Court No. 17–00173, Slip Op. 21–166 (CIT Dec. 8, 2021).

Timken Notice

In its decision in *Timken,*[15] as clarified by *Diamond Sawblades,*[16] the CAFC held that, pursuant to section 516A(c) and (e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of a court decision that is not ''in harmony'' with Commerce's determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's December 8, 2021, judgment constitutes a final decision of the CIT that is not in harmony with Commerce's *Amended Final Results.* Thus, this notice is published in fulfillment of the publication requirements of *Timken.*

Amended Final Results

Because there is now a final court judgment, Commerce is amending its *Final Results* and *Amended Final Results* with respect to Canadian Solar, Yingli and Shanghai BYD Co., Ltd. as follows:

Exporter	Weighted-average dumping margin (percent)
Canadian Solar International Limited; Canadian Solar Manufacturing (Changshu), Inc.; Canadian Solar Manufacturing (Luoyang), Inc.; CSI Cells Co., Ltd.; CSI–GCL Solar Manufacturing (YanCheng) Co., Ltd.; CSI Solar Power (China) Inc ...	0.00
Yingli Energy (China) Company Limited; Baoding Tianwei Yingli New Energy Resources Co., Ltd.; Tianjin Yingli New Energy Resources Co., Ltd.; Hengshui Yingli New Energy Resources Co., Ltd.; Lixian Yingli New Energy Resources Co., Ltd.; Baoding Jiasheng Photovoltaic Technology Co., Ltd.; Beijing Tianneng Yingli New Energy Resources Co., Ltd.; Hainan Yingli New Energy Resources Co., Ltd.; Shenzhen Yingli New Energy Resources Co., Ltd ...	0.00
Shanghai BYD Co., Ltd	0.00

Cash Deposit Requirements

Because Canadian Solar, Yingli, and Shanghai BYD Co., Ltd. all have a superseding cash deposit rate, *i.e.,* final results covering these companies have been published in a subsequent administrative review of the AD order on solar cells from China, we will not issue revised cash deposit instructions to U.S. Customs and Border Protection (CBP) in connection with this notice. Thus, this notice will not affect the current cash deposit rate of these companies.

Liquidation of Suspended Entries

At this time, Commerce remains enjoined, by orders of the CIT, from liquidating entries of subject merchandise that was entered, or withdrawn from warehouse, for consumption during the period December 1, 2014, through November 30, 2015 and produced and/or exported by the collapsed entity comprising Canadian Solar International Limited; Canadian Solar Manufacturing (Changshu), Inc.; Canadian Solar Manufacturing (Luoyang), Inc.; CSI Cells Co., Ltd.; CSI–GCL Solar Manufacturing (YanCheng) Co., Ltd.; and CSI Solar Power (China) Inc., or exported by any of the following entities: (1) the collapsed entity comprising Yingli Energy (China) Company Limited; Baoding Tianwei Yingli New Energy Resources Co., Ltd.; Tianjin Yingli New Energy Resources Co., Ltd.; Hengshui Yingli New Energy Resources Co., Ltd.; Lixian Yingli New Energy Resources Co., Ltd.; Baoding Jiasheng Photovoltaic Technology Co., Ltd.; Beijing Tianneng Yingli New Energy Resources Co., Ltd.; Hainan Yingli New Energy Resources Co., Ltd.; and Shenzhen Yingli New Energy Resources Co., Ltd.; (2) Shanghai BYD Co., Ltd.; (3) Ningbo Qixin Solar Electrical Appliance Co., Ltd.; (4) Chint Solar (Zhejiang) Co., Ltd.; (5) ERA Solar Co., Ltd.; (6) ET Solar Energy Limited; (7) Hangzhou Sunny Energy Science & Technology Co., Ltd.; (8) Hengdian Group DMEGC Magnetics Co., Ltd.; (9) JA Solar Technology Yangzhou Co., Ltd.; (10) Jiawei Solarchina (Shenzhen) Co., Ltd.; (11) Jiawei Solarchina Co., Ltd.; (12) JingAo Solar Co., Ltd.; (13) Lightway Green New Energy Co., Ltd.; (14) Ningbo ETDZ Holdings, Ltd.; (15) Risen Energy Co., Ltd.; (16) Shanghai JA Solar Technology Co., Ltd.; (17) Shenzhen Sungold Solar Co., Ltd.; (18) Shenzhen Topray Solar Co., Ltd.; (19) Star Power International Limited; (20) Systemes Versilis, Inc.; (21) Taizhou BD Trade Co., Ltd.; (22) tenKsolar (Shanghai) Co., Ltd.; (23) Toenergy Technology Hangzhou Co., Ltd.; (24) Wuxi Tianran Photovoltaic Co., Ltd.; (25) Zhejiang Era Solar Technology Co., Ltd.; and (26) Zhejiang Sunflower Light Energy Science & Technology Limited Liability Company. These entries will remain enjoined pursuant to the terms of injunctions during the pendency of any appeals process.

In the event the CIT's ruling is not appealed, or, if appealed, upheld by a final and conclusive court decision, Commerce intends to instruct CBP to assess antidumping duties on any unliquidated entries described in the preceding paragraph, in accordance with 19 CFR 351.212(b). We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when either the respondent's weighted-average dumping margin is not zero or *de minimis* or the importer-specific *ad valorem* assessment rate is not zero or *de minimis.* Where either the respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is *de minimis* (*i.e.,* less than 0.5 percent), we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[17]

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(c) and (e) and 777(i)(1) of the Act.

Dated: December 20, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, Performing the Non-Exclusive Functions and Duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021–28071 Filed 12–23–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–971]

Multilayered Wood Flooring From the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review, and Intent to Rescind Review, in Part; 2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to producers and exporters of multilayered wood flooring (wood flooring) from the People's Republic of China (China). The period of review (POR) is January 1, 2019, through December 31, 2019. Interested parties are invited to comment on these preliminary results of review.

DATES: Applicable December 27, 2021.

[15] *See Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

[16] *See Diamond Sawblades Manufacturers Coalition* v. United States, 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

[17] *See* 19 CFR 351.106(c)(2).

FOR FURTHER INFORMATION CONTACT: Dennis McClure, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5973.

SUPPLEMENTARY INFORMATION:

Background

On December 8, 2011, Commerce issued a countervailing duty (CVD) order on multilayered wood flooring from China.[1] Several interested parties requested that Commerce conduct an administrative review of the *Order.* On February 4, 2021, Commerce published in the **Federal Register** a notice of initiation of an administrative review of the *Order.*[2] On March 4 and October 7, 2021, we published in the **Federal Register** additional notices of initiation of an administrative review for two companies that were inadvertently excluded from the February 4, 2021 notice. Altogether, we initiated an administrative review of 171 producers/exporters for the POR.[3] On June 15, 2021, we rescinded this administrative review, in part, with respect to 88 companies, based on timely withdrawal of review requests.[4] For events that occurred since the *Initiation Notice, see* the Preliminary Decision Memorandum.[5]

Scope of the Order

The product covered by the *Order* is wood flooring from China. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Intent To Rescind Administrative Review, in Part

The following parties submitted no shipment certifications: Anhui Longhua Bamboo Product Co., Ltd. (Anhui); Benxi Flooring Factory (General Partnership) (Benxi); Dalian Deerfu Wooden Product Co., Ltd. (Deerfu); Dalian Shengyu Science and Technology Development Co., Ltd. (Shengyu); Dunhua Dexin Wood Industry Co., Ltd./Dunhua City Dexin Wood Industry Co., Ltd. (Dexin); Jiangsu Yuhui International Trade Co., Ltd. (Yuhui); Jiashan Fengyun Timber Co., Ltd. (Fengyun); Jiaxing Hengtong Wood Co., Ltd. (Hengtong); Kember Flooring, Inc. (Kember); Kingman Wood Industry Co., Ltd. (Kingman); Muchsee Wood (Chuzhou) Co., Ltd. (Muchsee); Power Dekor Group Co., Ltd. (Power Dekor); Yingyi-Nature (Kunshan) Wood Industry Co., Ltd. (Yingyi-Nature); Zhejiang Dadongwu Greenhome Wood Co., Ltd. (Dadongwu); Zhejiang Shiyou Timber Co., Ltd. (Shiyou); and Zhejiang Shuimojiangnan New Material Technology Co., Ltd. (New Material). Based on our analysis of U.S. Customs and Border Protection (CBP) information and comments received from interested parties, we preliminarily determine that eleven companies, Anhui; Benxi; Shengyu; Dexin; Yuhui; Kingman; Muchsee; Power Dekor; Yingyi-Nature; Shiyou; and New Material, had no shipments of subject merchandise during the POR.[6] [7] Absent any evidence of shipments placed on the record, pursuant to 19 CFR 351.213(d)(3), we intend to rescind the administrative review of these companies in the final results of review. Based on our analysis of CBP information and comments received from interested parties, we preliminarily determine that Kember, Hengtong and Dadongwu made shipments during the POR. For additional information regarding this determination, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we preliminarily determine that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that confers a benefit to the recipient, and that the subsidy is specific.[8] For a full description of the methodology underlying our preliminary conclusions, including our reliance, in part, on adverse facts available pursuant to sections 776(a) and (b) of the Act, *see* the Preliminary Decision Memorandum.

The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.* A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix I to this notice.

Preliminary Rate for Non-Selected Companies Under Review

As discussed above, Commerce initiated this administrative review on 171 producers/exporters; rescinded this administrative review, in part, with respect to 88 producers/exporters; and intends to rescind this review with respect to eleven companies that have certified no shipments during the POR. In addition, Commerce selected two mandatory respondents, Jiangsu Senmao Bamboo and Wood Industry Co., Ltd. (Jiangsu Senmao) and Riverside Plywood Corp. (Riverside Plywood) for individual examination.[9] For the remaining 67 companies subject this review, because the rates calculated for the mandatory respondents were above *de minimis* and not based entirely on facts available, we applied a subsidy rate based on a weighted-average of the subsidy rates calculated for Jiangsu Senmao and Riverside Plywood using publicly ranged sales data submitted by these mandatory respondents. This methodology to establish the all-others subsidy rate is consistent with our practice and section 705(c)(5)(A) of the Act. For further information on the calculation of the non-selected respondent rate, refer to the section in the Preliminary Decision Memorandum entitled ''Non-Selected Companies Under Review.'' For a list of the non-

[1] *See Multilayered Wood Flooring from the People's Republic of China: Countervailing Duty Order,* 76 FR 76693 (December 8, 2011) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 8166 (February 4, 2021) (*Initiation Notice*).

[3] Metropolitan Hardwood Floors, Inc. and Kember Flooring Inc., a.k.a. Kember Hardwood Flooring Inc. were inadvertently omitted from the initiation notice that published on February 4, 2021. *See also Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 12599 (March 4, 2021); and *Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 55811 (October 7, 2021).

[4] *See Multilayered Wood Flooring from the People's Republic of China: Partial Rescission of Countervailing Duty Administrative Review; 2019,* 86 FR 31696 (June 15, 2021) (*Partial Rescission*).

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Results in the Countervailing Duty Administrative Review of Multilayered Wood Flooring from the People's Republic of China; 2019,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *See* Memorandum, ''No Shipment Inquiry for Certain Companies During the Period 01/01/2019 through 12/31/2019,'' dated November 17, 2021.

[7] We did not consider Deerfu's no shipment certification and Fengyun's no shipment certification because we rescinded the review for these companies. *See Partial Rescission,* 86 FR at 31697.

[8] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[9] Cross-owned affiliates are Baroque Timber Industries (Zhongshan) Co., Ltd.; Suzhou Times Flooring Co., Ltd.; and Zhongshan Lianjia Flooring Co., Ltd.

selected companies, *see* Appendix II to this notice.

Preliminary Results of the Review

In accordance with 19 CFR 351.221(b)(4)(i), we calculated a countervailable subsidy rate for each of the mandatory respondents, Jiangsu Senmao and Riverside Plywood, and their cross-owned affiliates, where applicable.

We preliminarily find the countervailable subsidy rates for the mandatory and non-selected respondents under review to be as follows:

Producer/exporter	Subsidy rate (percent)
Riverside Plywood Corp. and its Cross-Owned Affiliates [10]	22.70
Jiangsu Senmao Bamboo and Wood Industry Co., Ltd	5.50
Non-Selected Companies Under Review [11]	15.71

Disclosure

We intend to disclose to interested parties the calculations performed for these preliminary results in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(3) of the Act, Commerce intends to verify the information relied upon for its final results. Normally, Commerce verifies information using standard procedures, including an on-site examination of original accounting, financial, and sales documentation. However, due to current travel restrictions in response to the global COVID–19 pandemic, Commerce is unable to conduct on-site verification in this review. Accordingly, we intend to verify the information relied upon for the final results through alternative means in lieu of an on-site verification.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance. A timeline for the submission of case and rebuttal briefs and written comments will be provided to interested parties at a later date.[12] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information until further notice.[13]

Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this review are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. 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 by telephone the date and time of the hearing two days before the scheduled date.

An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline.

Final Results

Unless extended, we intend to issue the final results of this administrative review, which will include the results of our analysis of the issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

Assessment Rates

In accordance with 19 CFR 351.221(b)(4)(i), we preliminarily assigned subsidy rates in the amounts shown above for the producer/exporters shown above. Upon completion of the administrative review, consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), Commerce shall determine, and CBP shall assess, countervailing duties on all appropriate entries covered by this review. For the companies for which this review is rescinded, Commerce will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2019, through December 31, 2019, in accordance with 19 CFR 351.212(c)(l)(i). Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication 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

In accordance with section 751(a)(1) of the Act, Commerce intends, upon publication of the final results, to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for each of the respective companies listed above and in Appendix II on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits at the most recent company-specific or all-others rate applicable to the company. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Interested Parties

These preliminary results are issued and published pursuant to sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: December 17, 2021.

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

Appendix II—Non-Selected Companies Under Review

1. Anhui Boya Bamboo & Wood Products Co., Ltd.

[10] Cross-owned affiliates are Baroque Timber Industries (Zhongshan) Co., Ltd.; Suzhou Times Flooring Co., Ltd.; and Zhongshan Lianjia Flooring Co., Ltd.

[11] *See* Appendix II.

[12] *See* 19 CFR 351.309(c) and (d).

[13] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 29615 (May 18, 2020); and *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

2. Anhui Yaolong Bamboo & Wood Products Co. Ltd.
3. Armstrong Wood Products (Kunshan) Co., Ltd.
4. Benxi Wood Company
5. Changzhou Hawd Flooring Co., Ltd.
6. Dalian Guhua Wooden Product Co., Ltd.
7. Dalian Huilong Wooden Products Co., Ltd.
8. Dalian Jaenmaken Wood Industry Co., Ltd.
9. Dalian Jiahong Wood Industry Co., Ltd.
10. Dalian Kemian Wood Industry Co., Ltd.
11. Dalian Penghong Floor Products Co., Ltd.
12. Dalian Qianqiu Wooden Product Co., Ltd.
13. Dalian Shumaike Floor Manufacturing Co., Ltd.
14. Dalian T-Boom Wood Products Co., Ltd.
15. Dongtai Fuan Universal Dynamics, LLC
16. Dun Hua Sen Tai Wood Co., Ltd.
17. Dunhua City Hongyuan Wood Industry Co., Ltd.
18. Dunhua City Jisen Wood Industry Co., Ltd.
19. Dunhua Shengda Wood Industry Co., Ltd.
20. Fine Furniture (Shanghai) Limited
21. Fusong Jinlong Wooden Group Co., Ltd.
22. Fusong Jinqiu Wooden Product Co., Ltd.
23. Fusong Qianqiu Wooden Product Co., Ltd.
24. Guangdong Yihua Timber Industry Co., Ltd.
25. Guangzhou Homebon Timber Manufacturing Co., Ltd.
26. HaiLin LinJing Wooden Products Co., Ltd.
27. Hangzhou Hanje Tec Company Limited
28. Hangzhou Zhengtian Industrial Co., Ltd.
29. Hunchun Forest Wolf Wooden Industry Co., Ltd.
30. Hunchun Xingjia Wooden Flooring Inc.
31. Huzhou Chenghang Wood Co., Ltd.
32. Huzhou Fulinmen Imp. & Exp. Co., Ltd.
33. Huzhou Jesonwood Co., Ltd.
34. Huzhou Sunergy World Trade Co., Ltd.
35. Jiangsu Guyu International Trading Co., Ltd.
36. Jiangsu Keri Wood Co., Ltd.
37. Jiangsu Mingle Flooring Co., Ltd.
38. Jiangsu Simba Flooring Co., Ltd.
39. Jiashan HuiJiaLe Decoration Material Co., Ltd.
40. Jiashan On-Line Lumber Co., Ltd.
41. Jiaxing Brilliant Import & Export Co., Ltd.
42. Jiaxing Hengtong Wood Co., Ltd.
43. Jilin Xinyuan Wooden Industry Co., Ltd.
44. Karly Wood Product Limited
45. Kember Flooring, Inc., a.k.a. Kember Hardwood Flooring, Inc.
46. Kemian Wood Industry (Kunshan) Co., Ltd.
47. Kingman Floors Co., Ltd.
48. Lauzon Distinctive Hardwood Flooring
49. Linyi Anying Wood Co., Ltd.
50. Linyi Youyou Wood Co., Ltd. (successor-in-interest to Shanghai Lizhong Wood Products Co., Ltd.) (a/k/a The Lizhong Wood Industry Limited Company of Shanghai)
51. Metropolitan Hardwood Floors, Inc.
52. Pinge Timber Manufacturing (Zhejiang) Co., Ltd.
53. Power Dekor North America Inc.
54. Scholar Home (Shanghai) New Material Co. Ltd.
55. Shanghaifloor Timber (Shanghai) Co., Ltd.
56. Sino-Maple (Jiangsu) Co., Ltd.
57. Suzhou Dongda Wood Co., Ltd.
58. Tongxiang Jisheng Import and Export Co., Ltd.
59. Xiamen Yung De Ornament Co., Ltd.
60. Xuzhou Shenghe Wood Co., Ltd.
61. Yekalon Industry, Inc.
62. Yihua Lifestyle Technology Co., Ltd.
63. Zhejiang Dadongwu GreenHome Wood Co., Ltd. (a.k.a. Zhejiang Dadongwu Greenhome Wood Co., Ltd. and Zhejiang Dadongwu Green Home Wood Co., Ltd.)
64. Zhejiang Fuerjia Wooden Co., Ltd.
65. Zhejiang Jiechen Wood Industry Co., Ltd.
66. Zhejiang Longsen Lumbering Co., Ltd.
67. Zhejiang Simite Wooden Co., Ltd.

[FR Doc. 2021–28074 Filed 12–23–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–979]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Notice of Court Decision Not in Harmony With the Results of Antidumping Duty Administrative Review; Notice of Amended Final Results

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On December 8, 2021, the U.S. Court of International Trade (CIT) issued its final judgment in *SolarWorld Americas, Inc., et al.* v. *United States,* Consol. Court No. 16–00134, sustaining the Department of Commerce (Commerce)'s fourth remand results pertaining to the administrative review of the antidumping duty (AD) order on crystalline silicon photovoltaic cells, whether or not assembled into modules (solar cells), from the People's Republic of China (China) covering the period December 1, 2013, through November 30, 2014. Commerce is notifying the public that the CIT's final judgment is not in harmony with the final results of the 2013–2014 AD administrative review of the solar cells from China and that Commerce is amending those final results with respect to the dumping margin assigned to the following companies: (1) The collapsed entity comprising Changzhou Trina Solar Energy Co., Ltd.; Trina Solar (Changzhou) Science and Technology Co., Ltd.; Yancheng Trina Solar Energy Technology Co., Ltd.; Changzhou Trina Solar Yabang Energy Co., Ltd.; Turpan Trina Solar Energy Co., Ltd.; and Hubei Trina Solar Energy Co., Ltd. (collectively, Trina); (2) Canadian Solar International Limited; (3) Canadian Solar Manufacturing (Changshu) Inc.; (4) Canadian Solar Manufacturing (Luoyang) Inc.; (5) BYD (Shangluo) Industrial Co., Ltd.; and (6) Shanghai BYD Co., Ltd.

DATES: Applicable December 18, 2021.

FOR FURTHER INFORMATION CONTACT: Jeff Pedersen, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2769.

SUPPLEMENTARY INFORMATION:

Background

On June 20, 2016, Commerce published the final results of the 2013–2014 AD administrative review of solar cells from China. In the *Final Results,* Commerce selected Thailand as the primary surrogate country and relied on Thai import data to value nitrogen that was used in manufacturing solar cells.[1]

Respondents, Trina, Canadian Solar Inc. et al., BYD (Shangluo) Industrial Co., Ltd., Shanghai BYD Co., Ltd., and Yingli,[2] and domestic interested party, SolarWorld Americas, Inc. (SolarWorld), challenged Commerce's *Final Results* (CIT case numbers 16–00132, 16–00134, and 16–00135). The CIT consolidated case numbers 16–00132, 16–00134, and 16–00135 into case number 16–00134 in October 2016. On October 18, 2017, the CIT sustained Commerce's *Final Results* with respect to: (1) The surrogates that it selected to value aluminum frames, semi-finished polysilicon ingots and blocks, solar backsheets, nitrogen, and financial ratios; and (2) its application of adverse facts available with respect to unreported factors of production. However, the CIT remanded the *Final Results* to Commerce to reconsider, or further explain: (1) The surrogates that it selected to value tempered glass and scrapped solar cells and modules; and (2) its decision to include import values with zero import quantities in its surrogate value calculations.[3]

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2013–2014,* 81 FR 39905 (June 20, 2016) (*Final Results*), and accompanying Issues and Decision Memorandum at Comment 21.

[2] We used ''Yingli'' to refer to the following companies that we treated as a single entity: Yingli Energy (China) Company Limited; Baoding Tianwei Yingli New Energy Resources Co., Ltd.; Tianjin Yingli New Energy Resources Co., Ltd.; Hengshui Yingli New Energy Resources Co., Ltd.; Lixian Yingli New Energy Resources Co., Ltd.; Baoding Jiasheng Photovoltaic Technology Co., Ltd.; Beijing Tianneng Yingli New Energy Resources Co., Ltd.; Hainan Yingli New Energy Resources Co., Ltd.; and Shenzhen Yingli New Energy Resources Co., Ltd.

[3] *See SolarWorld Americas, Inc.et al.* v. *United States,* 273 F. Supp. 3d 1254 (CIT 2017).

In its first remand redetermination, issued in January 2018, Commerce further explained its surrogate value selections for tempered glass and scrapped solar cells and modules and explained why it was appropriate to include import values with zero import quantities in its surrogate value calculations.[4] The CIT sustained Commerce's redetermination with respect to including imports with zero quantities in its surrogate value calculations, but remanded to Commerce for a second time its choice of surrogates to value tempered glass and scrapped solar cells and modules.[5]

In its second remand redetermination, issued in July 2018, Commerce reexamined its selection of the surrogate values at issue and, under respectful protest, valued tempered glass using Bulgarian import data rather than Thai import data and valued scrapped solar cells and modules using a different Thai tariff system classification number.[6] The CIT sustained Commerce's second redetermination.[7] Commerce published a notice of a court decision that was not in harmony with the final results of its review on February 1, 2019.[8]

Trina and SolarWorld appealed various aspects of the CIT's final decision to the U.S. Court of Appeals for the Federal Circuit (CAFC). On June 24, 2020, the CAFC affirmed the CIT's judgment: (1) Sustaining Commerce's inclusion of imports with zero quantities in surrogate value calculations; (2) Commerce's valuation of backsheets; and (3) remanding to Commerce to further justify, or reconsider, the surrogate that it selected to value tempered glass. However, the CAFC vacated the CIT's judgment sustaining Commerce's selection of a surrogate to value nitrogen and remanded the case for further proceedings consistent with its opinion.[9]

In its third remand redetermination, issued in January 2021, Commerce continued to value nitrogen using Thai import data. Specifically, in its third remand redetermination Commerce explained why it did not find the average unit value (AUV) of Thai imports of nitrogen during the period of review (POR) to be aberrational, clarified its practice for evaluating whether an AUV from a surrogate country is aberrational, and addressed the discrepancies between U.S. POR exports of nitrogen to Thailand and Thai POR imports of nitrogen from the United States.[10] The CIT remanded the case to Commerce for a fourth time, ordering Commerce to reconsider, or further explain, its use of Thai import data to value nitrogen.[11]

In its final remand redetermination, issued in September 2021, under respectful protest, Commerce used Bulgarian import data, rather than Thai import data, to value nitrogen.[12] The CIT sustained Commerce's final redetermination.[13]

Timken Notice

In its decision in *Timken,*[14] as clarified by *Diamond Sawblades,*[15] the CAFC held that, pursuant to section 516A(c) and (e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of a court decision that is not ''in harmony'' with Commerce's determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's December 8, 2021 judgment constitutes a final decision of the CIT that is not in harmony with Commerce's *Final Results.* Thus, this notice is published in fulfillment of the publication requirements of *Timken.*

Amended Final Results

Because there is now a final court judgment, Commerce is amending its *Final Results* and *Timken Notice and Amended Final Results* with respect to Trina, Canadian Solar International Limited; Canadian Solar Manufacturing (Changshu) Inc.; Canadian Solar Manufacturing (Luoyang) Inc.; BYD (Shangluo) Industrial Co., Ltd.; and Shanghai BYD Co., Ltd. as follows:

Exporters	Weighted-average dumping margin (percent)
Changzhou Trina Solar Energy Co., Ltd.; Trina Solar (Changzhou) Science and Technology Co., Ltd.; Yancheng Trina Solar Energy Technology Co., Ltd.; Changzhou Trina Solar Yabang Energy Co., Ltd.; Turpan Trina Solar Energy Co., Ltd.; Hubei Trina Solar Energy Co., Ltd	0.00
Canadian Solar International Limited	0.00
Canadian Solar Manufacturing (Changshu) Inc	0.00
Canadian Solar Manufacturing (Luoyang) Inc	0.00
BYD (Shangluo) Industrial Co., Ltd	0.00
Shanghai BYD Co., Ltd	0.00

Cash Deposit Requirements

Because Trina, Canadian Solar International Limited; Canadian Solar Manufacturing (Changshu) Inc.; Canadian Solar Manufacturing (Luoyang) Inc.; and Shanghai BYD Co., Ltd. all have a superseding cash deposit rate, *i.e.,* final results covering these companies have been published in a subsequent administrative review of the AD order on solar cells from China, we will not issue revised cash deposit instructions to U.S. Customs and Border Protection (CBP) in connection with

[4] *See* Final Results of Remand Redetermination, *SolarWorld Americas, Inc.* v. *United States,* Court No. 16–00134, Slip Op. 17–143 (Court of International Trade October 18, 2017), dated January 18, 2018.

[5] *See SolarWorld Americas, Inc. et al.* v. *United States,* 320 F. Supp. 3d 1341 (CIT 2018).

[6] *See SolarWorld Americas, Inc.* v. *United States,* Court No. 16–00134, Slip Op. 18–53 (Court of International Trade June 18, 2018) Results of Second Remand Redetermination Pursuant to Court Order, dated July 31, 2018.

[7] *See SolarWorld Americas, Inc. et al.* v. *United States,* 355 F. Supp. 3d 1306 (CIT 2018).

[8] *See Crystalline Silicon Photovoltaic Cells, Whether or not Assembled Into Modules, from the People's Republic of China: Notice of Court Decision Not in Harmony with Final Results of Antidumping Duty Administrative Review,* 84 FR 1053 (February 1, 2019) (*Timken Notice and Amended Final Results*).

[9] *See SolarWorld Americas, Inc. et al.* v. *United States,* 962 F.3d 1351 (Fed. Cir. 2020).

[10] *See SolarWorld Americas, Inc. et al.* v. *United States,* Consol. Court No. 16–00134 (CIT September 2, 2020), Final Results of Redetermination Pursuant to Court Remand, dated January 14, 2021.

[11] *See SolarWorld Americas, Inc. et al.* v. *United States,* 532 F. Supp. 3d 1266 (CIT 2021).

[12] *See SolarWorld Americas, Inc., et al.* v. *United States,* Consol. Court No. 16–00134 (CIT July 28, 2021), Final Results of Redetermination Pursuant to Court Remand, dated September 27, 2021.

[13] *See SolarWorld Americas, Inc. et al.* v. *United States,* Consol. Court No. 16–00134, Slip Op. 21–165 (CIT December 8, 2021).

[14] *See Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

[15] See *Diamond Sawblades Manufacturers Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

these companies. Thus, this notice will not affect the current cash deposit rate of these companies. However, we will issue revised cash deposit instructions to CBP for BYD (Shangluo) Industrial Co., Ltd.

Liquidation of Suspended Entries

At this time, Commerce remains enjoined, by orders of the CIT, from liquidating entries of subject merchandise that was entered, or withdrawn from warehouse, for consumption during the period December 1, 2013 through November 30, 2014 and exported by any of the following companies: (1) Trina; (2) Canadian Solar International Limited; (3) Canadian Solar Manufacturing (Changshu) Inc.; (4) Canadian Solar Manufacturing (Luoyang) Inc.; (5) BYD (Shangluo) Industrial Co., Ltd.; (6) Shanghai BYD Co., Ltd.; (7) Wuxi Suntech Power Co., Ltd/Luoyang Suntech Power Co., Ltd.; (8) Dongguan Sunworth Solar Energy Co., Ltd.; (9) ERA Solar Co., Ltd.; (10) ET Solar Energy Limited; (11) JA Solar Technology Yangzhou Co., Ltd.; (12) Jiangsu High Hope Int'l Group; (13) JingAo Solar Co., Ltd.; (14) Ningbo Qixin Solar Electrical Appliance Co., Ltd.; (15) Shenzhen Glory Industries Co., Ltd.; and (16) Shenzhen Topray Solar Co., Ltd. These entries will remain enjoined pursuant to the terms of the injunctions during the pendency of any appeals process.

In the event the CIT's ruling is not appealed, or, if appealed, upheld by a final and conclusive court decision, Commerce intends to instruct CBP to assess antidumping duties on any unliquidated entries described in the preceding paragraph, in accordance with 19 CFR 351.212(b). We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when either the respondent's weighted-average dumping margin is not zero or *de minimis* or the importer-specific *ad valorem* assessment rate is not zero or *de minimis.* Where either the respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is *de minimis* (*i.e.,* less than 0.5 percent), we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[16]

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(c) and (e) and 777(i)(1) of the Act.

[16] *See* 19 CFR 351.106(c)(2).

Dated: December 20, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, Performing the Non-Exclusive Functions and Duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021–28072 Filed 12–23–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–054]

Certain Aluminum Foil From the People's Republic of China: Final Results of Countervailing Duty Administrative Review; 2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of certain aluminum foil (aluminum foil) from the People's Republic of China (China). The period of review (POR) is January 1, 2019, through December 31, 2019.

DATES: Applicable December 27, 2021.

FOR FURTHER INFORMATION CONTACT: Tyler Weinhold, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1121.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Results* of this review on July 7, 2021, and invited comments from interested parties.[1] On August 13, 2021, we received timely filed case briefs from the following interested parties: Jiangsu Zhongji Lamination Materials Co., Ltd. (Zhongji); Xiamen Xiashun Aluminum Foil Co., Ltd. (Xiashun); and the Government of China (GOC).[2] On August 24, 2021, we received a timely filed rebuttal brief from the Aluminum Association Trade Enforcement Working Group (the petitioners).[3]

Scope of the Order

The product covered by this order is aluminum foil from China.[4] For a complete description of the scope of this order, *see* the Issues and Decision Memorandum.[5]

Analysis of Comments Received

All issues raised in interested parties' case briefs are addressed in the Issues and Decision Memorandum. A list of the issues raised by parties to which Commerce responded in the Issues and Decision Memorandum is provided in Appendix I to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on the comments received and record evidence, we made certain changes from the *Preliminary Results* with respect to the net countervailable subsidy rate calculated for Xiashun and assigned to companies not selected for individual examination in this review. These changes are explained in the Issues and Decision Memorandum.

Methodology

Commerce conducted this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we find that there is a subsidy, *i.e.,* a government-provided financial contribution that gives rise to a benefit to the recipient,

[1] *See Certain Aluminum Foil from the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review and Rescission of Review, in Part; 2019,* 86 FR 35735 (July 7, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Zhongji's Case Brief, ''Certain Aluminum Foil from the People's Republic of China: Case Brief,'' dated August 13, 2021 (Zhonji's Case Brief); Xiashun's Case Brief, ''Certain Aluminum Foil from The People's Republic of China—Case Brief,'' dated August 13, 2021 (Xiashun's Case Brief); and GOC's Case Brief, ''Certain Aluminum Foil from the People's Republic of China: Case Brief,'' dated August 13, 2021 (GOC's Case Brief).

[3] *See* Petitioner's Rebuttal Brief, ''Certain Aluminum Foil from The People's Republic Of China . . . Petitioners' Rebuttal Brief,'' dated August 24, 2021 (the Petitioner's Rebuttal Brief). Individual Members of the Aluminum Association Trade Enforcement Working Group include: JW Aluminum Company, Novelis Corporation, and Reynolds consumer Products LLC.

[4] *See Certain Aluminum Foil from the People's Republic of China: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 76 FR 17360 (April 19, 2018) (*Order*).

[5] *See* Memorandum, ''Decision Memorandum for the Final Results of the 2019 Administrative Review of the Countervailing Duty Order on Certain Aluminum Foil from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

and that the subsidy is specific.[6] For a full description of the methodology underlying all of Commerce's conclusions, including any determination that relied upon the use of adverse facts available pursuant to sections 776(a) and (b) of the Act, *see* the Issues and Decision Memorandum.

Companies Not Selected for Individual Examination

In accordance with 19 CFR 351.221(b)(5), Commerce calculated a countervailable subsidy rate for mandatory respondent Xiashun. Because the rate calculated for Xiashun, the only cooperating mandatory respondent, is above *de minimis* and not based entirely on facts available, we assigned this rate to other companies subject to this administrative review but not selected for individual examination. This is consistent with the methodology that we use in an investigation to establish the all-others rate, pursuant to section 705(c)(5)(A) of the Act.

Final Results of Administrative Review

We determine that, for the period January 1, 2019, through December 31, 2019, the following net countervailable subsidy rates exist:

Company	Net countervailable subsidy rate (percent *ad valorem*)
Alcha International Holdings Limited	14.20
Anhui Maximum Aluminum Industries Company Ltd.; Jiangsu Huafeng Aluminum Industry Co., Ltd.; Jiangsu Zhongji Lamination Materials Co., Ltd.; Jiangsu Zhongji Lamination Materials Co., (HK) Limited; and Shantou Wanshun Package Material Stock Co., Ltd.[7]	14.20
Dingsheng Aluminum Industries (Hong Kong) Trading Co., Ltd.; Hangzhou DingCheng Aluminum Co., Ltd.; Hangzhou Dingsheng Import & Export Co. Ltd.; Hangzhou Dingsheng Industrial Group Co. Ltd.; Hangzhou Five Star Aluminum Co., Ltd.; Hangzhou Teemful Aluminum Co., Ltd.; Jiangsu Dingsheng New Materials Joint Stock Co., Ltd.; Luoyang Longding Aluminium Industries Co., Ltd.; and Walson (HK) Trading Co., Limited.[8]	14.20
Hunan Suntown Marketing Limited	14.20
Jiangsu Alcha Aluminum Co., Ltd.	305.07
SNTO International Trade Limited	14.20
Suntown Technology Group Corporation Limited	14.20
Xiamen Xiashun Aluminium Foil Co. Ltd.	14.20
Yinbang Clad Material Co., Ltd.	14.20

Disclosure

Commerce intends to disclose the calculations performed for these final results of review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rate

Pursuant to 19 CFR 351.212(b)(2), Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries of subject merchandise in accordance with the final results of this review, for the above-listed companies at the applicable *ad valorem* assessment rates listed. Consistent with its recent notice,[9] Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication 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 Rates

In accordance with section 751(a)(1) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for each of the companies listed above. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposits, when imposed, shall remain in effect until further notice.

Administrative Protective Order

This notice also serves as a final reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notice to Interested Parties

These final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

[6] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[7] In the first administrative review of the *Order,* Commerce found the following companies to be cross-owned: Anhui Maximum Aluminum Industries Company Ltd.; Jiangsu Huafeng Aluminum Industry Co. Ltd.; Jiangsu Zhongji Lamination Materials Co., Ltd.; Jiangsu Zhongji Lamination Materials Co., (HK) Ltd.; Shantou Wanshun Material Stock Co., Ltd.; and Anhui Maximum Aluminum Industries Company Limited. The subsidy rate applies to all cross-owned companies. *See Certain Aluminum Foil from the People's Republic of China: Final Results of the Countervailing Duty Administrative Review; 2017–2018,* 86 FR 12171 (March 2, 2021).

[8] In the investigation, Commerce found the following companies to be cross-owned: Dingsheng Aluminum Industries (Hong Kong) Trading Co., Ltd.; Hangzhou DingCheng Aluminum Co., Ltd.; Hangzhou Dingsheng Import & Export Co. Ltd.; Hangzhou Dingsheng Industrial Group Co. Ltd.; Hangzhou Five Star Aluminum Co., Ltd.; Hangzhou Teemful Aluminum Co., Ltd.; Jiangsu Dingsheng New Materials Joint-Stock Co., Ltd.; Luoyang Longding Aluminum Co., Ltd.; and Walson (HK) Trading Co., Limited. The subsidy rate applies to all cross-owned companies. *See Order.*

[9] *See Notice of Discontinuation of Policy to Issue Liquidation Instructions After 15 Days in Applicable Antidumping and Countervailing Duty Administrative Proceedings,* 86 FR 3995 (January 15, 2021).

Dated: December 17, 2021.

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 Issues and Decision Memorandum

[FR Doc. 2021–28043 Filed 12–23–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–095]

Aluminum Wire and Cable From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is conducting an administrative review of the antidumping duty (AD) order on aluminum wire and cable from the People's Republic of China (China) covering the period June 5, 2019, through November 30, 2020. We determine that ICF Cable and Jin Tiong Electrical Materials Manufacturer PTE, Limited (Jin Tiong) are not eligible for a separate rate, and, therefore, are part of the China-wide entity.

DATES: Applicable December 27, 2021.

FOR FURTHER INFORMATION CONTACT: Sean Carey, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3964.

SUPPLEMENTARY INFORMATION:

Background

On September 2, 2021, the Department of Commerce (Commerce) published its preliminary results of the administrative review of the antidumping duty order on aluminum wire and cable from the People's Republic of China (China).[1] The domestic interested parties in this review are Encore Wire Corporation and Southwire Company, LLC (collectively, the petitioners for the original less-than-fair-value investigation). The companies subject to this administrative review are ICF Cable and Jin Tiong. A complete summary of the events that occurred since publication of the *Preliminary Determination,* as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.[2]

Scope of the Order

The products covered by the order are aluminum wire and cable from China. For a full description of the scope of the order, *see* ''Scope of the Order,'' in the appendix of the *Preliminary Results.*

Analysis of Comments Received

We addressed all issues raised in the case and rebuttal briefs submitted by parties in this review in the Issues and Decision Memorandum, which is hereby adopted by this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* A list of topics discussed in the Issues and Decision Memorandum is included as an appendix to this notice. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Review

We made no changes to the *Preliminary Results* and continue to find that both ICF Cable and Jin Tiong are not eligible for a separate rate because neither company established its eligibility for a separate rate. Therefore, we continue to find both ICF Cable and Jin Tiong to be part of the China-wide entity.

In this administrative review, no party requested a review of the China-wide entity, and Commerce did not initiate a review of the China-wide entity. Because no review of the China-wide entity has been initiated, the China-wide entity's entries are not subject to the review, and the weighted-average dumping margin applicable to the China-wide entity is not subject to change as a result of this review. The existing weighted-average dumping margin, and, therefore, the applicable cash deposit rate and assessment rate for antidumping duties, is 52.79 percent, the rate established in the final determination of the less-than-fair-value investigation.[3]

Disclosure and Public Comment

Normally, Commerce discloses the calculations used in its analysis to parties in a review within five days of the date of publication of the notice of final results, in accordance with 19 CFR 351.224(b). However, in this review, there are no calculations on the record to disclose.

Assessment Rates

Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries in accordance with section 751(a)(2)(C) of the Act and 19 CFR 351.212(b). Because we determined that ICF Cable and Jin Tiong are not eligible for a separate rate and are part

[1] *See Aluminum Wire and Cable from the People's Republic of China: Preliminary Results of Antidumping Administrative Review; 2019–2020,* 86 FR 49306 (September 2, 2021) (*Preliminary Results*).

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of Antidumping Duty Administrative Review: Aluminum Wire and Cable from the People's Republic of China; 2019–2020,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See Aluminum Wire and Cable from the People's Republic of China: Antidumping Duty and Countervailing Duty Orders,* 84 FR 70496, 70497 (December 23, 2019).

of the China-wide entity, we will instruct CBP to apply an *ad valorem* assessment rate for antidumping duties of 52.79 percent to all entries of subject merchandise during the POR that were exported by ICF Cable and Jin Tiong.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication 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 upon publication of the final results of this administrative review for shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For previously investigated or reviewed Chinese or non-Chinese exporters that received a separate rate in a prior completed segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (2) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the cash deposit rate for the China-wide entity (*i.e.,* 52.79 percent); and (3) for all non-Chinese exporters of subject merchandise that have not received their own separate rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties or countervailing duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping or countervailing duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Orders

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results of administrative review in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h).

Dated: December 20, 2021.

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

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2021–28042 Filed 12–23–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–970]

Multilayered Wood Flooring From the People's Republic of China: Preliminary Results of the Antidumping Duty Administrative Review, Preliminary Determination of No Shipments, and Rescission of Review, in Part; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that Jiangsu Senmao Bamboo and Wood Industry Co., Ltd. (Senmao) did not make sales of subject merchandise at less than normal value (NV), and that certain companies had no shipments of subject merchandise during the period of review (POR) December 1, 2019, through November 30, 2020. In addition, we are rescinding the review with respect to one company. We invite interested parties to comment on these preliminary results.

DATES: Applicable December 27, 2021.

FOR FURTHER INFORMATION CONTACT: Sergio Balbontin or Alexis Cherry, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6478 or (202) 482–0607, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce is conducting an administrative review of the antidumping duty order on multilayered wood flooring (MLWF) from the People's Republic of China (China).[1] The review covers 96 companies, including mandatory respondent, Senmao.

For events that occurred since the *Initiation Notice* and the analysis behind our preliminary results herein, *see* the Preliminary Decision Memorandum.[2] The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.* A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix I to this notice.

Scope of the Order [3]

The product covered by the *Order* is MLWF from China. For a complete

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 8166 (February 4, 2021); and *Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 17124 (April 1, 2021) (collectively, *Initiation Notices).*

[2] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Multilayered Wood Flooring from the People's Republic of China; 2019–2020,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[3] *See Multilayered Wood Flooring from the People's Republic of China: Notice of Amended Final Affirmative Determination of Sales at Less*

description of the scope of this administrative review, *see* the Preliminary Decision Memorandum.

Partial Rescission of Review

On May 3, 2021, the American Manufacturers of Multilayered Wood Flooring (the petitioner) and Kingman Floors Co., Ltd. (Kingman Floors) timely withdrew their requests for review with respect to Kingman Floors.[4] No other parties requested a review of this company. Accordingly, Commerce is rescinding the administrative review with respect to Kingman Floors.[5]

Preliminary Determination of No Shipments

Based on an analysis of information from U.S. Customs and Border Protection (CBP), no shipment certifications, and other record information, we preliminarily determine that 41 companies had no shipments of subject merchandise during the POR. Consistent with our practice in non-market economy (NME) cases, we are not rescinding this review with respect to these companies but, rather, intend to complete the review and issue appropriate instructions to CBP based on the final results of the review.[6]

Separate Rates

We preliminarily determine that, in addition to Senmao, 10 companies not individually-examined are eligible for separate rates in this administrative review.[7] The Tariff Act of 1930, as amended (the Act) and Commerce's regulations do not address the establishment of a separate rate to be applied to companies not selected for individual 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 an investigation, for guidance when calculating the rate for separate-rate respondents which Commerce did not examine individually in an administrative review. For the preliminary results of this review, Commerce has determined the estimated dumping margin for Senmao to be zero.[8] For the reasons explained in the Preliminary Decision Memorandum, we are assigning this rate to the non-examined respondents which qualify for a separate rate in this review.

The China-Wide Entity

Commerce's policy regarding conditional review of the China-wide entity applies to this administrative review.[9] Under this policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the China-wide entity, the entity is not under review, and the entity's rate (*i.e.* 85.13 percent) is not subject to change. *See* the Preliminary Decision Memorandum for further discussion.

Aside from the companies for which we preliminarily find no shipments and the company for which the review is being rescinded, Commerce considers all other companies for which a review was requested and did not demonstrate separate rate eligibility to be part of the China-wide entity.[10] For the preliminary results of this review, we consider 43 companies to be part of the China-wide entity.

Methodology

We are conducting this administrative review in accordance with sections 751(a)(1)(B) of the Act and 19 CFR 351.213. We calculated export prices for Senmao in accordance with section 772(a) of the Act. Because China is an NME within the meaning of section 771(18) of the Act, we calculated NV in accordance with section 773(c) of the Act.

Preliminary Results of Review

We preliminarily determine that the following weighted-average dumping margins exist for the POR December 1, 2019, through November 30, 2020:

Exporters	Weighted-average dumping margin (percent)
Jiangsu Senmao Bamboo and Wood Industry Co., Ltd	00.00
Non-Selected Companies Under Review Receiving a Separate Rate[11]	00.00

Disclosure and Public Comment

We intend to disclose to interested parties the calculations performed for these preliminary results in accordance with 19 CFR 351.224(b). A timeline for the submission of case briefs and written comments will be provided to interested parties at a later date. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline date for case briefs.[12] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this review are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. Executive summaries should be limited to five pages total, including footnotes. Case and rebuttal briefs should be filed using ACCESS[13] and must be served on interested parties.[14] Note that Commerce has modified certain of its requirements for serving documents containing business proprietary information until further notice.[15]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically via Commerce's electric records system, ACCESS. An electronically-filed request must be received successfully in its entirety by 5:00 p.m. Eastern Time within 30 days after the date of

than Fair Value and Antidumping Duty Order, 76 FR 76690 (December 8, 2011), as amended in *Multilayered Wood Flooring from the People's Republic of China,* 77 FR 5484 (February 3, 2012) (collectively, *Order*).

[4] *See* Petitioner's Letter, ''Withdrawal of Request for Administrative Review in Part''; and Kingman Floors' Letter, ''Withdrawal of Request for Administrative Review of the Antidumping Duty Order,'' both dated May 3, 2021.

[5] *See* 19 CFR 351.213(d)(1).

[6] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65694–95 (October 24, 2011) (*NME AD Assessment*); *see also* the ''Assessment Rates'' section, below.

[7] *See* Appendix II; *see also* the Preliminary Decision Memorandum at the ''Separate Rate Determinations'' section for more details.

[8] *See* Memorandum, ''Preliminary Results Margin Calculation for Jiangsu Senmao Bamboo and Wood Industry Co., Ltd.,'' dated concurrently with this notice.

[9] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[10] *See Initiation Notice* (''All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below.'') Companies that are subject to this administrative review that are considered to be part of the China-wide entity are listed in Appendix II.

[11] *See* Appendix II.

[12] *See* 19 CFR 351.309(d); *see* also *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006, 17007 (March 26, 2020) (''To provide adequate time for release of case briefs via ACCESS, E&C intends to schedule the due date for all rebuttal briefs to be 7 days after case briefs are filed (while these modifications remain in effect).'')

[13] *See generally* 19 CFR 351.303.

[14] *See* 19 CFR 351.303(f).

[15] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

publication of this notice.[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. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined.[17] Parties should confirm by telephone the date and time of the hearing two days before the scheduled date.

Unless otherwise extended, we intend to issue the final results of this administrative review, which will include the results of our analysis of the issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register,** pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

Verification

As provided in section 782(i)(3) of the Act, Commerce intends to verify the information relied upon for its final results. Normally, Commerce verifies information using standard procedures, including an on-site examination of original accounting, financial, and sales documentation. However, due to current travel restrictions in response to the global COVID–19 pandemic, Commerce is unable to conduct on-site verification in this review. Accordingly, we intend to verify the information relied upon for the final results through alternative means in lieu of an on-site verification.

Assessment Rates

Upon issuance of the final results, Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review, in accordance with 19 CFR 351.212(b). Commerce intends to issue assessment instructions to CBP 35 days after the publication of the final results of this review.

If Senmao's *ad valorem* weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.50 percent) in the final results of this review, Commerce will calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales and the total quantity of those sales, in accordance with 19 CFR 351.212(b)(1).[18] Commerce will also calculate (estimated) *ad valorem* importer-specific assessment rates with which to assess whether the per-unit assessment rate is *de minimis.* We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific *ad valorem* assessment rate calculated in the final results of this review is not zero or *de minimis.*

For the respondents that were not selected for individual examination in this administrative review that qualified for a separate rate, the assessment rate will be the separate rate established in the final results of this administrative review.

If, in the final results, Senmao's weighted-average dumping margin continues to be zero or *de minimis* (*i.e.,* less than 0.5 percent), Commerce will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[19] For entries that were not reported in the U.S. sales databases submitted by Senmao during this review, and for the 43 companies that do not qualify for a separate rate, Commerce will instruct CBP to liquidate such entries at the China-wide rate (*i.e.,* 85.13 percent).[20] In addition, if we continue to find no shipments of subject merchandise for the 41 companies for which we preliminarily find no such shipments during the POR,[21] any suspended entries of subject merchandise associated with those companies will be liquidated at the China-wide rate.[22]

For the company for which the administrative review is rescinded, antidumping duties shall be assessed at a rate equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i).

We intend to issue appropriate assessment instructions with respect to the company for which this administrative review is rescinded to CBP 35 days after the publication of the final results 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 upon publication of the final results of this review for all shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the companies listed above that have a separate rate, the cash deposit rate will be that rate established in the final results of this review (except, if the rate is *de minimis,* then a cash deposit rate of zero will be required); (2) for previously investigated or reviewed Chinese and non-Chinese exporters for which a review was not requested and that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the China-wide entity (*i.e.,* 85.13 percent); and (4) for all non-Chinese exporters of subject merchandise that have not received their own rate, the cash deposit rate will be the rate applicable to Chinese exporter that supplied that non-Chinese exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing the preliminary results of this review in accordance with sections 751(a)(l) and 777(i)(l) of the Act and 19 CFR 351.221(b)(4).

[16] *See* 19 CFR 351.310(c)

[17] *See* 19 CFR 351.310(d).

[18] In these preliminary results, Commerce applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

[19] *See* 19 CFR 351.106(c)(2).

[20] *See Multilayered Wood Flooring from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2016–2017,* 84 FR 38002 (August 5, 2019).

[21] *See* Appendix II for a list of these companies.

[22] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65695 (October 24, 2011).

Dated: December 17, 2021.

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

Appendix II

No Shipments:

Anhui Longhua Bamboo Product Co., Ltd.
Arte Mundi (Shanghai) Aesthetic Home Furnishings Co., Ltd. (successor-in-interest to Scholar Home (Shanghai) New Material Co., Ltd.) [23]
Baroque Timber Industries (Zhongshan) Co., Ltd.
Benxi Wood Company
Dalian Deerfu Wooden Product Co., Ltd.
Dalian Jaenmaken Wood Industry Co., Ltd.
Dalian Jiahong Wood Industry Co., Ltd.
Dalian Shengyu Science And Technology Development Co., Ltd.
Dongtai Fuan Universal Dynamics, LLC
Dunhua City Dexin Wood Industry Co., Ltd.
Dunhua City Hongyuan Wood Industry Co., Ltd.
Dunhua City Jisen Wood Industry Co., Ltd.
Fine Furniture (Shanghai) Limited
HaiLin LinJing Wooden Products Co., Ltd.
Hunchun Xingjia Wooden Flooring Inc.
Huzhou Chenghang Wood Co., Ltd
Huzhou Fulinmen Imp. & Exp. Co., Ltd.
Huzhou Sunergy World Trade Co., Ltd.
Jiangsu Keri Wood Co., Ltd.
Jiangsu Mingle Flooring Co., Ltd
Jiangsu Simba Flooring Co., Ltd.
Jiangsu Yuhui International Trade Co., Ltd.
Jiashan On-Line Lumber Co., Ltd.
Jiaxing Hengtong Wood Co., Ltd.
Jilin Xinyuan Wooden Industry Co., Ltd.
Kember Flooring, Inc. (a.k.a. Kember Hardwood Flooring, Inc.)
Linyi Anying Wood Co., Ltd.
Linyi Youyou Wood Co., Ltd.
Muchsee Wood (Chuzhou) Co., Ltd.
Pinge Timber Manufacturing (Zhejiang) Co., Ltd.
Power Dekor Group Co., Ltd.
Sino-Maple (Jiangsu) Co., Ltd.
Suzhou Dongda Wood Co., Ltd.
Tongxiang Jisheng Import and Export Co., Ltd.
Yekalon Industry Inc.
Yihua Lifestyle Technology Co., Ltd. (successor-in-interest to Guangdong Yihua Timber Industry Co., Ltd.)
Yingyi-Nature (Kunshan) Wood Industry Co., Ltd.
Zhejiang Dadongwu Greenhome Wood Co., Ltd.
Zhejiang Longsen Lumbering Co., Ltd.
Zhejiang Shiyou Timber Co., Ltd.
Zhejiang Shuimojiangnan New Material Technology Co., Ltd.

China-Wide Entity:

A & W (Shanghai) Woods Co., Ltd.
Anhui Boya Bamboo & Wood Products Co., Ltd.
Anhui Yaolong Bamboo & Wood Products Co. Ltd.
Armstrong Wood Products (Kunshan) Co., Ltd.
Armstrong World Industries Inc.
Changzhou Hawd Flooring Co., Ltd.
Chinafloors Timber (China) Co., Ltd.
Dalian Dajen Wood Co., Ltd.
Dalian Guhua Wooden Product Co., Ltd.
Dalian Huade Wood Product Co., Ltd.
Dalian Huilong Wooden Products Co., Ltd.
Dalian Kemian Wood Industry Co., Ltd.
Dalian Qianqiu Wooden Product Co., Ltd., Fusong Jinlong Wooden Group Co., Ltd., Fusong Jinqiu Wooden Product Co., Ltd., and Fusong Qianqiu Wooden Product Co., Ltd. (collectively, Fusong Jinlong Group)
Dalian T-Boom Wood Products Co., Ltd.
Guangzhou Homebon Timber Manufacturing Co., Ltd.
Guangzhou Panyu Kangda Board Co., Ltd.
Guangzhou Panyu Southern Star Co., Ltd.
Hangzhou Hanje Tec Company Limited
Hangzhou Zhengtian Industrial Co., Ltd.

Hunchun Forest Wolf Wooden Industry Co., Ltd.
Huzhou Jesonwood Co., Ltd.
Innomaster Home (Zhongshan) Co., Ltd.
Jiafeng Wood (Suzhou) Co., Ltd.
Jilin Forest Industry Jinqiao Flooring Group Co., Ltd.
Karly Wood Product Limited
Kemian Wood Industry (Kunshan) Co., Ltd.
Linyi Bonn Flooring Manufacturing Co., Ltd.
Mudanjiang Bosen Wood Industry Co., Ltd.
Nakahiro Jyou Sei Furniture (Dalian) Co., Ltd.
Omni Arbor Solution Co., Ltd.
Power Dekor North America Inc.
Shandong Longteng Wood Co., Ltd.
Shanghai Lairunde Wood Co., Ltd.
Shanghaifloor Timber (Shanghai) Co., Ltd.
Shenyang Haobainian Wooden Co., Ltd.
Shenzhenshi Huanwei Woods Co., Ltd.
Xiamen Yung De Ornament Co., Ltd.
Xuzhou Antop International Trade Co., Ltd.
Xuzhou Shenghe Wood Co., Ltd.
Zhejiang Biyork Wood Co., Ltd.
Zhejiang Fudeli Timber Industry Co., Ltd.
Zhejiang Jiechen Wood Industry Co., Ltd.
Zhejiang Simite Wooden Co., Ltd.

Rescissions:

Kingman Floors Co., Ltd.

Non-Selected Companies Under Review Receiving a Separate Rate:

Benxi Flooring Factory (General Partnership)
Dalian Penghong Floor Products Co., Ltd./Dalian Shumaike Floor Manufacturing Co., Ltd.
Dun Hua Sen Tai Wood Co., Ltd.
Dunhua Shengda Wood Industry Co., Ltd
Jiangsu Guyu International Trading Co., Ltd
Jiashan HuiJiaLe Decoration Material Co., Ltd.
Kingman Wood Industry Co., Ltd.
Lauzon Distinctive Hardwood Flooring, Inc.
Metropolitan Hardwood Floors, Inc.
Zhejiang Fuerjia Wooden Co., Ltd.

[FR Doc. 2021–28069 Filed 12–23–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB674]

South Atlantic Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a special meeting via webinar to discuss development of its Allocations Decision Tool.

DATES: The Council meeting will be held from 1 p.m. until 5 p.m. on Monday, February 7, 2022.

ADDRESSES:

Meeting address: The meeting will be held via webinar. Webinar registration is required. See **SUPPLEMENTARY INFORMATION.**

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 20405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 302–8440 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: Meeting information, including the webinar registration link, agenda, briefing book materials and an online comment form will be posted on the Council's website at: *http://safmc.net/safmc-meetings/council-meetings/.*

The Council will focus discussion on its Allocation Decision Tool, which has been under development since 2020. The Council will apply the decision tool, as currently drafted, to Greater Amberjack to determine its functionality and discuss changes that should be made as well as how it will be best utilized to inform sector allocation decisions for other managed species in the future.

Comments may be submitted through the online form on the Council's website *http://safmc.net/safmc-meetings/council-meetings/* beginning on Monday, January 24, 2022, and through 5 p.m. on February 7, 2022. Written comments may be directed to John Carmichael, Executive Director, South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 20405.

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 Council's intent to take final action to address the emergency.

[23] Arte Mundi Group Co. Ltd. (Arte Mundi Group), submitted a timely no shipment certification in which it reported that Arte Mundi Shanghai changed its name to Arte Mundi Group during the POR, however, the company did not respond to Commerce's successor-in-interest questionnaire. Therefore, we did not make a no-shipments determination with respect to Arte Mundi Group. *See* the Preliminary Determination Memorandum for further details.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 5 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: December 21, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–28011 Filed 12–23–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB673]

South Atlantic Fishery Management Council (Council); Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce

ACTION: Notice of scoping meetings and open public comment.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a series of scoping meetings via webinar pertaining to Amendments 51, 52, and 53 to the Fishery Management Plan (FMP) for the Snapper Grouper Fishery of the South Atlantic Region. The amendments adjust catch levels for snowy grouper, golden tilefish, and gag based on results of the latest stock assessments for those species, respectively, and consider adjusting management measures where needed. In addition, Amendment 52 considers changes to recreational accountability and management measures for blueline tilefish. The Council is also soliciting input on ways to reduce the number of released fish and improve the survival of released fish by the snapper grouper fishery in the South Atlantic region. The Council intends to develop a Release Mortality Reduction Framework Amendment to address this issue across the fishery and revise red snapper catch levels.

DATES: The scoping meetings for Amendments 51, 52, and 53 will be held via webinar on February 1, 2 and 3, 2022. Comments on approaches to curb release mortality are being solicited online only at this time to assist the Council in narrowing down options that can be explored further. Scoping hearings for the resulting amendment will be held later in 2022.

ADDRESSES: *Council address:* South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 571–4366 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: The scoping meetings for Amendments 51, 52, and 53 will be conducted via webinar. The scoping meetings will begin at 6 p.m. Registration for the webinars is required. Registration information, a summary of the issues to be scoped, an online public comment form and any additional information will be posted on the Council's website at *https://safmc.net/safmc-meetings/public-hearings-scoping-meetings/* by January 18, 2022.

An online public comment form to gather input on approaches to reduce release mortality in the snapper grouper fishery will be posted on the Council's website at: *https://safmc.net/safmc-meetings/public-hearings-scoping-meetings/.* Public comments on all the topics must be received by 5 p.m. on February 4, 2022.

Amendment 51 to the Snapper Grouper FMP

The Council must adjust catch levels for snowy grouper in response to the most recent stock assessment for the species in the region conducted through the Southeast Data, Assessment, and Review (SEDAR) stock assessment process, SEDAR 36 Update (2020). The assessment indicated the stock continues to be overfished and is undergoing overfishing. A rebuilding plan is already in place for snowy grouper; however, catch levels must be adjusted based on the new acceptable biological catch recommended by the Council's Scientific and Statistical Committee (SSC). In addition, the Council is considering modifications to annual catch limits, sector allocations, accountability measures, and management measures.

Amendment 52 to the Snapper Grouper FMP

The stock of golden tilefish in the South Atlantic was most recently assessed through SEDAR 66 (2020), which indicated the stock is not overfished nor undergoing overfishing but is near the overfishing threshold. The Council must adjust catch levels based on the new recommended acceptable biological catch, review sector allocations, and consider whether other modifications to the management of golden tilefish are needed at this time. In the same amendment, the Council is also considering revising recreational management measures and accountability measures for blueline tilefish.

Amendment 53 to the Snapper Grouper FMP

Results of SEDAR 71 (2021) indicated the gag stock in the South Atlantic is overfished and undergoing overfishing. A rebuilding plan is being considered in this amendment to rebuild the stock and adjust fishing mortality to end overfishing. In addition to adjusting catch levels and sector allocations, the Council is exploring modifications to management measures and accountability measures. During the scoping meetings, Council staff will present an overview of the issues and will be available to answer questions via webinar. Members of the public will have an opportunity to go on record to provide their comments for consideration by the Council.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 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: December 21, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–28013 Filed 12–23–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB664]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the U.S. Coast Guard's Base Los Angeles/Long Beach Wharf Expansion Project, Los Angeles, California

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of incidental harassment authorization.

SUMMARY: NMFS has received a request from the U.S. Coast Guard (Coast Guard) for the re-issuance of a previously issued incidental harassment authorization (IHA) with the only change being effective dates. The initial IHA authorized take of five species of marine mammals, by Level A and Level B harassment, incidental to construction associated with the Base Los Angeles/Long Beach Wharf Expansion Project in Los Angeles, California. The project has been delayed and none of the work covered in the initial IHA has been conducted. The Coast Guard has requested re-issuance with new effective dates of February 1, 2022 through January 31, 2023. The scope of the activities and anticipated effects remain the same, authorized take numbers are not changed, and the required mitigation, monitoring, and reporting remains the same as included in the initial IHA. NMFS is, therefore, issuing a second identical IHA to cover the incidental take analyzed and authorized in the initial IHA.

DATES: This authorization is effective from February 1, 2022 through January 31, 2023.

ADDRESSES: An electronic copy of the final 2021 IHA previously issued to the Coast Guard, the re-issued IHA, the original application, and the **Federal Register** notices proposing and issuing the initial IHA may be obtained by visiting *https://www.fisheries.noaa.gov/action/incidental-take-authorization-us-coast-guard-base-los-angeles-wharf-expansion-ca.* In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Dwayne Meadows, Ph.D., Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the Marine Mammal Protection Act (MMPA; 16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

The MMPA states that the term ''take'' means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On December 11, 2020, NMFS published final notice of our issuance of an IHA authorizing take of marine mammals incidental to the Base Los Angeles/Long Beach Wharf Expansion Project (85 FR 80044). The effective dates of that IHA were February 1, 2021, through January 31, 2022. On March 16, 2021, the Coast Guard informed NMFS that the project was delayed. None of the work identified in the initial IHA (*e.g.,* pile driving) has occurred. The Coast Guard submitted a request for a new identical IHA that would be effective from February 1, 2022 through January 31, 2023, in order to conduct the construction work that was analyzed and authorized through the previously issued IHA. Therefore, re-issuance of the IHA is appropriate.

Summary of Specified Activity and Anticipated Impacts

The planned activities (including mitigation, monitoring, and reporting), authorized incidental take, and anticipated impacts on the affected stocks are the same as those analyzed and authorized through the previously issued IHA.

The purpose of the Coast Guard's construction project is to expand the existing wharf and other base infrastructure for hosting two additional offshore patrol cutters. The location, timing, and nature of the activities, including the types of equipment planned for use, are identical those described in the initial IHA. The mitigation and monitoring are also as prescribed in the initial IHA.

Species that are expected to be taken by the planned activity include harbor seals (*Phoca vitulina*), California sea lions (*Zalophus californianus*), Bottlenose dolphins (*Tursiops truncatus*), Short-beaked common dolphin (*Delphinus delphis*), and gray whales (*Eschrichtius robustus*). A description of the methods and inputs used to estimate take anticipated to occur and, ultimately, the take that was authorized is found in the previous documents referenced above. The data inputs and methods of estimating take are identical to those used in the initial IHA. NMFS has reviewed recent Stock Assessment Reports, information on relevant Unusual Mortality Events, and recent scientific literature, and determined that no new information affects our original analysis of impacts or take estimate under the initial IHA.

We refer to the documents related to the previously issued IHA, which include the **Federal Register** notice of the issuance of the initial 2021 IHA for the Coast Guard's construction work (85 FR 80044), the Coast Guard's application, the **Federal Register** notice of the proposed IHA (85 FR 66939; October 21, 2020), and all associated references and documents.

Determinations

The Coast Guard will conduct activities as analyzed in the initial 2021 IHA. As described above, the number of authorized takes of the same species and stocks of marine mammals are identical to the numbers that were found to meet the negligible impact and small numbers standards and authorized under the initial IHA and no new information has emerged that would change those findings. The re-issued IHA includes identical required mitigation, monitoring, and reporting measures as the initial IHA, and there is no new information suggesting that our analysis or findings should change.

Based on the information contained here and in the referenced documents, NMFS has determined the following: (1) The required mitigation measures will effect the least practicable impact on marine mammal species or stocks and their habitat; (2) the authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the authorized takes represent small numbers of marine

mammals relative to the affected stock abundances; and (4) GCHS' activities will not have an unmitigable adverse impact on taking for subsistence purposes as subsistence harvest of harbor seals and other marine mammals is rare in the area and local subsistence users have not expressed concern about this project.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action with respect to environmental consequences on the human environment.

Accordingly, NMFS has determined that the issuance of the IHA qualifies to be categorically excluded from further NEPA review. This action is consistent with categories of activities identified in CE B4 of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion.

Endangered Species Act (ESA)

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat.

No incidental take of ESA-listed species is authorized or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

Authorization

NMFS has issued an IHA to the Coast Guard for in-water construction activities associated with the specified activity from February 1, 2022 through January 31, 2023. All previously described mitigation, monitoring, and reporting requirements from the initial 2021 IHA are incorporated.

Dated: December 21, 2021.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–27993 Filed 12–23–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB680]

Gulf of Mexico Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of hybrid meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will hold a four-day meeting to consider actions affecting the Gulf of Mexico fisheries in the exclusive economic zone (EEZ). The meeting is open to the public offering both in-person and virtual options for participation.

DATES: The meeting will convene Monday, January 24 through Wednesday, January 26, 2022, from 8 a.m. to 5:30 p.m., CST and on Thursday, January 27, 2022, from 8 a.m. to 4:30 p.m., CST.

ADDRESSES:

Meeting address: The meeting will take place at Hilton Baton Rouge Capitol Center, located at 201 Lafayette Street, Baton Rouge, LA 70801. Please note, in-person meeting attendees will be expected to follow any current COVID–19 safety protocols as determined by the Council, hotel and the City of Baton Rouge. Such precautions may include masks, room capacity restrictions, and/or social distancing. If you prefer to ''listen in'', you may access the log-on information by visiting our website at *www.gulfcouncil.org.*

Council address: Gulf of Mexico Fishery Management Council, 4107 W. Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Dr. Carrie Simmons, Executive Director, Gulf of Mexico Fishery Management Council; telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION:

Monday, January 24, 2022; 8 a.m.–5:30 p.m., CST

The meeting will begin open to the public in a Full Council Session to hold an Election of Council Vice-Chair, and review and adoption of the revised Council Committee Assignments for October 2021 through August 2022.

Committee sessions will begin approximately 8:15 a.m. with the Habitat Protection and Restoration Committee receiving a presentation from the Bureau of Ocean Energy Management (BOEM) on Wind Energy Development in the Gulf of Mexico, review of Essential Fish Habitat Generic Amendment and Draft Response Letter to NOAA Request for Comments on the Area-Based Management Goals Related to Executive Order 14008.

The Outreach and Education Committee will receive a presentation on 2021 Communications Analytics and Updated 2021 Communications Improvement Plan, draft Social Media Guidelines, draft Public Comment Guidelines, draft Press Release Guidelines, and the 2022 Communications Improvement Plan. The Committee will discuss remaining items form the Outreach and Education Technical Committee and receive a presentation on Summary of Discard and Barotrauma Reduction Efforts Across the Region.

The Shrimp Committee will review National Marine Fisheries Service's (NMFS) Evaluation of Draft Approval Specifications for Reinstituting Historical cELB Program, Updated Draft Framework Action: Modification of the Vessel Position Data Collection Program for the Gulf of Mexico Shrimp Fishery, and summary of the Shrimp Advisory Panel Meeting.

The Mackerel Committee will review and discuss Coastal Migratory Pelagics Landings, Draft Amendment 33: Modifications to the Gulf of Mexico Migratory Group King Mackerel Catch Limits and Sector Allocations, and Draft Amendment 34: Atlantic Migratory Group King Mackerel Catch Levels and Atlantic King and Spanish Mackerel Management Measures.

Tuesday, January 25, 2022; 8 a.m.–5:30 p.m., CST

The Reef Fish Committee will convene to review Reef Fish Landings and Individual Fishing Quota (IFQ) Landings and Final Action: Framework Action: Modification of Vermillion Snapper Catch Limits. Following, the Committee will receive presentations on SEDAR 70: Greater Amberjack Stock Assessment Report and SEDAR 72: Gag Grouper Stock Assessment Report, and discuss SSC Recommendations and Reef Fish Advisory Panel Feedback for both. The Committee will also discuss the Council Request for State Reef Fish Survey (SRFS) Integration and Update Assessment for SEDAR 72: Gag Grouper.

The Committee will review Individual Fishing Quota (IFQ) Programs, Focus Group Formation and next steps and Public Hearing Draft: Reef Fish Amendment 36B. The Committee will receive an update on Draft Snapper Grouper Amendment 44 and Reef Fish Amendment 55: Modifications to Southeastern U.S. Yellowtail Snapper

Jurisdictional Allocations, Catch Limits, and South Atlantic Sector Annual Catch Limits.

The Committee will hold a discussion on Wenchman in the Gulf of Mexico, review the Revised Great Red Snapper Count Estimates and SSC Recommendations for re-evaluating Red Snapper Catch Advise, discuss any remaining SSC and Reef Fish Advisory Panel recommendations.

Full Council will reconvene in a CLOSED SESSION for selection of IFQ Focus Group Participants.

Wednesday, January 26, 2022; 8 a.m.–5:30 p.m., CST

The Data Collection Committee will receive an update on Southeast For-Hire Integrated Electronic Reporting (SEFHIER) Program and review Draft Framework Action: Modification to Location Reporting Requirements for For-Hire Vessels and Reef Fish Advisory Panel (AP) Recommendations. The Committee will receive a presentation on Update on Modifications to the Commercial Electronic Reporting Program. The Committee will receive an update on Upcoming Workshop to Evaluate State-federal Recreational Survey Differences.

The Sustainable Fisheries Committee will review and discuss Standardized Bycatch Reporting Methodology and SSC Recommendations.

Following lunch at approximately 1:30 p.m. CST, the Council will reconvene with a Call to Order, Announcements and Introductions, Adoption of Agenda and Approval of Minutes; and receive a presentation on Density Estimations of age-0 and age-1 Gray Triggerfish, *Balistes capriscus,* and Vermilion Snapper, *Rhomboplites aurorubens,* from 2007 to 2015, in the northern Gulf of Mexico.

The Council will hold public testimony from 2:15 p.m. to 5:30 p.m., CST on Final Action Item: Framework Action: Modification of Vermilion Snapper Catch Limits*;* and open testimony on other fishery issues or concerns. Public comment may begin earlier than 2:15 p.m. CST, but will not conclude before that time. Persons wishing to give public testimony in-person must register at the registration kiosk in the meeting room. Persons wishing to give public testimony virtually must sign up on the Council website on the day of public testimony. Registration for virtual testimony closes one hour (1:15 p.m. CST) before public testimony begins.

Thursday, January 27, 2022; 8 a.m.–4:30 p.m., CST

The Council will receive Committee reports from Habitat Protection and Restoration, Shrimp, Outreach and Education, Mackerel, Data Collection, Reef Fish and Sustainable Fisheries Management Committees. The Council will review Closed Session Report and receive updates from the following supporting agencies: South Atlantic Fishery Management Council; Louisiana Law Enforcement Efforts; NOAA Office of Law Enforcement (OLE); Gulf States Marine Fisheries Commission; U.S. Coast Guard; U.S. Fish and Wildlife Service; and Department of State.

Lastly, the Council will discuss any Other Business items.

Meeting Adjourns

The meeting will be a hybrid meeting offering options for both in-person and virtual attendance. You may register for the webinar to ''listen-in'' only by visiting *www.gulfcouncil.org* and click on the Council meeting tab.

The timing and order in which agenda items are addressed may change as required to effectively address the issue, and the latest version along with other meeting materials will be posted on the website as they become available.

Although other non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during these meeting. Actions will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided that the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid or accommodations should be directed to Kathy Pereira, (813) 348–1630, at least 15 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 21, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–28073 Filed 12–23–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB677]

North Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of webconference.

SUMMARY: The North Pacific Fishery Management Council (NPFMC) Ecosystem Committee will meet January 25, 2022 through January 26, 2022.

DATES: The meeting will be held on Tuesday, January 25, 2022, through Wednesday, January 26, 2022, from 8 a.m. to 4 p.m., Alaska Time.

ADDRESSES: The meeting will be a webconference. Join online through the link at *https://meetings.npfmc.org/Meeting/Details/2481.*

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave., Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions for attending the meeting are given under **SUPPLEMENTARY INFORMATION**, below.

FOR FURTHER INFORMATION CONTACT: Diana Evans, Council staff; phone; (907) 271–2809 and email: *diana.evans@noaa.gov.* For technical support please contact administrative Council staff, email: *npfmc.admin@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Agenda

Tuesday, January 25, 2022 Through Wednesday, January 26, 2022

The Ecosystem Committee agenda will include discussion of the NOAA marine debris activities, northern fur seal co-management updates, essential fish habitat model development, forage fish research in Alaska, a planning update for the Council's ecosystem workshop, discussion of the Committee role, and other business. The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/2481* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone; or by phone only. Connection information will be posted online at: *https://meetings.npfmc.org/Meeting/Details/2481.*

Public Comment

Public comment letters will be accepted and should be submitted electronically to *https://meetings.npfmc.org/Meeting/Details/2481.*

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 21, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–28012 Filed 12–23–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB663]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Army Corps of Engineers Debris Dock Replacement Project, Sausalito, California

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of incidental harassment authorization.

SUMMARY: NMFS has received a request from the U.S. Army Corps of Engineers (ACOE) for the re-issuance of a previously issued incidental harassment authorization (IHA) with the only change being effective dates. The initial IHA authorized take of seven species of marine mammals, by Level A and Level B harassment, incidental to construction associated with the Debris Dock Replacement Project in Sausalito, California. The project has been delayed and none of the work covered in the initial IHA has been conducted. The initial IHA was effective from September 1, 2021, through August 31, 2022. The ACOE has requested re-issuance with new effective dates of January 5, 2022 through January 4, 2023. The scope of the activities and anticipated effects remain the same, authorized take numbers are not changed, and the required mitigation, monitoring, and reporting remains the same as included in the initial IHA. NMFS is, therefore, issuing a second identical IHA to cover the incidental take analyzed and authorized in the initial IHA.

DATES: This authorization is effective from January 5, 2022 through January 4, 2023.

ADDRESSES: An electronic copy of the final 2021 IHA previously issued to the ACOE, the ACOE's application, and the **Federal Register** notices proposing and issuing the initial IHA may be obtained by visiting */www.fisheries.noaa.gov/action/incidental-take-authorization-army-corps-engineers-debris-dock-replacement-project-sausalito.* In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Dwayne Meadows, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the Marine Mammal Protection Act (MMPA; 16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

The MMPA states that the term ''take'' means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On July 14, 2021, NMFS published final notice of our issuance of an IHA authorizing take of marine mammals incidental to the Debris Dock Replacement project (86 FR 37124). The effective dates of that IHA were September 1, 2021, through August 31, 2022. On December 14, 2021, the ACOE informed NMFS that the project was delayed. None of the work identified in the initial IHA (*e.g.,* pile driving and removal) has occurred. The ACOE submitted a request that we reissue an identical IHA that would be effective from January 5, 2022 through January 4, 2023, in order to conduct the construction work that was analyzed and authorized through the previously issued IHA. Therefore, re-issuance of the IHA is appropriate.

Summary of Specified Activity and Anticipated Impacts

The planned activities (including mitigation, monitoring, and reporting), authorized incidental take, and anticipated impacts on the affected stocks are the same as those analyzed and authorized through the previously issued IHA.

The purpose of the ACOE's construction project is to replace the existing decaying dock and other onshore infrastructure used to move marine debris collected from San Francisco Bay onto land for disposal. The location, timing, and nature of the activities, including the types of equipment planned for use, are identical to those described in the initial IHA. The mitigation and monitoring are also as prescribed in the initial IHA.

Species that are expected to be taken by the planned activity include harbor porpoise (*Phocoena phocoena*), harbor seal (*Phoca vitulina*), gray whale (*Eschrichtius robustus*), bottlenose dolphin (*Tursiops truncatus*), California sea lion (*Zalophus californianus*), northern fur seal (*Callorhinus ursinus*), and northern elephant seal (*Mirounga angustirostris*). A description of the methods and inputs used to estimate take anticipated to occur and, ultimately, the take that was authorized is found in the previous documents referenced above. The data inputs and methods of estimating take are identical to those used in the initial IHA. NMFS has reviewed recent Stock Assessment Reports, information on relevant Unusual Mortality Events, and recent scientific literature, and determined that no new information affects our original analysis of impacts or take estimate under the initial IHA.

We refer to the documents related to the previously issued IHA, which include the **Federal Register** notice of the issuance of the initial 2021 IHA for the ACOE's construction work (86 FR 37124), the ACOE's application, the **Federal Register** notice of the proposed IHA (86 FR 28768), and all associated references and documents.

Determinations

The ACOE will conduct activities as analyzed in the initial 2021 IHA. As described above, the number of authorized takes of the same species and stocks of marine mammals are identical to the numbers that were found to meet the negligible impact and small numbers standards and authorized under the initial IHA and no new information has emerged that would change those findings. The re-issued 2022 IHA includes identical required mitigation, monitoring, and reporting measures as the initial IHA, and there is no new information suggesting that our analysis or findings should change.

Based on the information contained here and in the referenced documents, NMFS has determined the following: (1) The required mitigation measures will effect the least practicable impact on marine mammal species or stocks and their habitat; (2) the authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the authorized takes represent small numbers of marine mammals relative to the affected stock abundances; and (4) the ACOE's activities will not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action with respect to environmental consequences on the human environment.

Accordingly, NMFS has determined that the issuance of the IHA qualifies to be categorically excluded from further NEPA review. This action is consistent with categories of activities identified in CE B4 of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion.

Endangered Species Act (ESA)

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

However, no incidental take of ESA-listed species is authorized or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

Authorization

NMFS has issued an IHA to the ACOE for in-water construction activities associated with the specified activity from January 5, 2022 through January 4, 2023. All previously described mitigation, monitoring, and reporting requirements from the initial 2021 IHA are incorporated.

Dated: December 21, 2021.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–27991 Filed 12–23–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB676]

North Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a hybrid public meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) Crab Plan Team will meet January 10, 2022, through January 14, 2022.

DATES: The meeting will be held on Monday, January 10, 2022, from 10 a.m. to 5:30 p.m., Tuesday, January 11, 2022 through Thursday, January 13, 2022 from 8 a.m. to 5 p.m. and on Friday, January 14, 2022, from 8 a.m. to 12 p.m., Alaska Time.

ADDRESSES: The meeting will be a hybrid meeting. Attend in-person at the Anchorage Hilton Hotel, 500 W 3rd Ave., Anchorage, AK 99501 or join online through the link at *https://meetings.npfmc.org/Meeting/Details/2733.*

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave., Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions for attending the meeting via video conference are given under **SUPPLEMENTARY INFORMATION**, below.

FOR FURTHER INFORMATION CONTACT: Diana Stram, Council staff; phone; (907) 271–2809; email: *diana.stram@noaa.gov.* For technical support please contact our admin Council staff, email: *npfmc.admin@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Agenda

January 10, 2022, through Friday, January 14, 2022

The agenda will include: (a) Survey updates for Bristol Bay Red King Crab (BBRKC) resampling; (b) economic stock assessment and fishery evaluation (SAFE); (c) Norton Sound Red King Crab (NSRKC) final assessment and stock status; (d) Alaska Climate Integrated Modeling (ACLIM) management scenarios for Bering Sea stocks; (e) ecological and socioeconomic profile (ESP) update on snow crab indicator development; (f) snow crab collapse hypotheses and analyses; (g) snow crab rebuilding discussion; (h) Aleutian Island Golden King Crab (AIGKC) model explorations; (i) alternatives to mature male biomass (MMB); (j) stock assessment terms of reference (TOR); (k) risk table future direction; (l) Bering Sea Fisheries Research Foundation (BSFRF) update; (m) modeling workshop and (n) other business. The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/2733* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone, or by phone only. Connection information will be posted online at: *https://meetings.npfmc.org/Meeting/Details/2733.* If you are attending the meeting in-person, please note that all attendees will be required to wear a mask.

Public Comment

Public comment letters will be accepted and should be submitted electronically to *https://meetings.npfmc.org/Meeting/Details/2733.*

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 21, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–28014 Filed 12–23–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Limitations on Terms of Consumer Credit Extended to Service Members and Dependents—Military Lending Act Database; Notice of Database Update

AGENCY: The Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Notice of database update.

SUMMARY: The Department of Defense (the Department) is providing notice to the public of a scheduled change to the Military Lending Act (MLA) Database. This update adds cadets and midshipmen attending Military Service Academies of the Armed Forces, who are covered borrowers under the MLA, to the population of covered borrowers identified in the MLA database, thereby correcting an error in the database's original development. The MLA applies to consumer credit extended to members of the Armed Forces and their dependents, as enacted by Congress in the National Defense Authorization Act for Fiscal Year 2013. The MLA statute requires the Secretary of Defense to prescribe regulations to carry out the MLA, and such regulations were published on July 22, 2015. This change to the MLA database is administrative in nature and does not change the current MLA regulation nor does it change the status of the cadets and midshipmen attending the Military Service Academies of the Armed Forces. Therefore, this announcement is not subject to notice and comment rulemaking under the Administrative Procedures Act (APA).

DATES: This change to the database will be effective February 1, 2022.

FOR FURTHER INFORMATION CONTACT: Andrew Cohen, (703) 692–5286.

SUPPLEMENTARY INFORMATION: The MLA statute and regulation applies to consumer credit extended to members of the armed forces and their dependents, otherwise known as a ''covered borrower'' as enacted by Congress in the National Defense Authorization Act for Fiscal Year 2013. The MLA statute requires the Secretary of Defense to prescribe regulations to carry out 10 U.S.C. 987. The Secretary of Defense prescribed required regulations published in 32 CFR part 232 on July 22, 2015.

In prescribing regulations to implement the statute, the Department provided creditors an optional safe harbor provision if they conclusively determined whether credit is offered or extended to a ''covered borrower'', and thus may be subject to 10 U.S.C. 987 and the requirements of this part, by assessing the status of a consumer in accordance with the regulation. *See* 32 CFR 232.5. A ''covered borrower'' is a consumer who, at the time the consumer becomes obligated on a consumer credit transaction or establishes an account for consumer credit, is a ''covered member'' or a dependent of a covered member. *See* 32 CFR 323.3. The regulation provides a creditor two methods to conclusively determine whether credit being offered or extended to an individual is a covered borrower for the purpose of the MLA.

These methods are:

A. The use of the Department's MLA database. ''[A] creditor may verify the status of a consumer by using information relating to that consumer, if any, obtained directly or indirectly from the database maintained by the Department, available at *https://www.dmdc.osd.mil/mla/welcome.xhtml.* A search of the Department's database requires the entry of the consumer's last name, date of birth, and Social Security number.'' *See* 32 CFR 232.5(b)(2)(i)(A). Or,

B. The use of a consumer report from a nationwide consumer reporting agency. ''To determine whether a consumer is a covered borrower, a creditor may verify the status of a consumer by using a statement, code, or similar indicator describing that status, if any, contained in a consumer report obtained from a consumer reporting agency that compiles and maintains files on consumers on a nationwide basis, or a reseller of such a consumer report (as each of those terms is defined in the Fair Credit Reporting Act (15 U.S.C. 1681a) and any implementing regulation (12 CFR part 1022)).'' *See* 32 CFR 232.5(b)(2)(ii).

While the cadets and midshipmen of the military academies of the armed forces meet the requirement of being a ''member of the armed forces who is serving on—''(i) Active duty pursuant to title 10, title 14, or title 32, United States Code, under a call or order that does not specify a period of 30 days or fewer'', they are currently not included in the population of the MLA database as they should be. This change remediates that condition.

Dated: December 20, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2021–28034 Filed 12–23–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2021–SCC–0143]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; International Resource Information System (IRIS)

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without change of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before January 26, 2022.

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 information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox. Comments may also be sent to *ICDocketmgr@ed.gov.*

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Sara Starke, (202) 453–7681.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education 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: International Resource Information System (IRIS).

OMB Control Number: 1840–0759.

Type of Review: Extension without change of a currently approved collection.

Respondents/Affected Public: Private Sector; Individuals or Households; Federal Government.

Total Estimated Number of Annual Responses: 6,596.

Total Estimated Number of Annual Burden Hours: 35,712.

Abstract: Information Resource Information System (IRIS) is an online performance reporting system for grantees of International and Foreign Language Education (IFLE) programs. The site also allows for IFLE program officers to process overseas language requests, travel authorization requests, and grant activation requests. IRIS keeps a record of these requests and also of Foreign Language and Area Studies (FLAS) Fellowship recipients and grantee performance reports.

Dated: December 20, 2021.

Kate 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. 2021–27933 Filed 12–23–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2021–SCC–0124]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Impact Evaluation of Training in Multi-Tiered Systems of Support for Reading in Early Elementary School

AGENCY: Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before January 26, 2022.

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 information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox. Comments may also be sent to *ICDocketmgr@ed.gov.*

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Lauren Angelo, 202–245–7474.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education 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: Impact Evaluation of Training in Multi-Tiered Systems of Support for Reading in Early Elementary School.

OMB Control Number: 1850–0953.

Type of Review: A revision of a currently approved collection.

Respondents/Affected Public: Individuals and Households; State, Local, and Tribal Governments

Total Estimated Number of Annual Responses: 24,465.

Total Estimated Number of Annual Burden Hours: 5,301.

Abstract: This study will provide much needed evidence on strategies to support US students' development of foundational reading skills, essential to later learning.

A third of US students fail to develop foundational reading skills by 4th grade that are necessary to succeed academically. In addition, the achievement gap is growing as demonstrated by The Nation's Report Card. To address this, the Every Student Succeeds Act (ESSA) promotes the use of evidence-based literacy interventions. And, the Department of Education (ED) has made supporting educators with the knowledge, skills, professional development, or materials necessary to improve reading instruction a key priority. The Individuals with Disabilities Education Act (IDEA) similarly encourages high quality instruction along with better identification of students needing extra support to prevent or mitigate student reading issues.

This study will provide much needed evidence by evaluating two professional development strategies for bolstering core reading instruction and supplemental supports, guided by data, within a MTSS–R framework. MTSS–R is a widely used framework for providing high-quality reading instruction for all students, identifying students needing supplemental or more intensive supports, and providing these additional supports for those who need it.

Dated: December 21, 2021.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021–28061 Filed 12–23–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Common Instructions for Applicants to Department of Education Discretionary Grant Programs

AGENCY: Office for Planning, Evaluation and Policy Development, Department of Education.

ACTION: Notice; revised common instructions.

SUMMARY: On February 13, 2019, the Department of Education (Department) published a set of common instructions

for applicants seeking funds under a Department discretionary grant competition as part of a broader effort to reduce barriers for applicants. These common instructions are referenced in individual competition notices inviting applications (NIAs). In this notice, we are publishing a revised version of the common instructions that supersedes the version published on February 13, 2019.

FOR FURTHER INFORMATION CONTACT: Ronald B. Petracca, U.S. Department of Education, 400 Maryland Avenue SW, Room 6E306, Washington, DC 20202. Telephone: (202) 401–6008. Email: *Ronald.Petracca@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Background: This document provides applicants with a centralized and up-to-date set of instructions for applying to the Department's discretionary grant programs. Future NIAs will reference this document in lieu of providing this series of instructions within each NIA. Rarely, exceptions will need to be made to these instructions and will be noted in an individual competition NIA.

Revised Common Instructions

The Department is making several changes to the common instructions for applicants provided in the notice published in the **Federal Register** on February 13, 2019 (84 FR 3768). Throughout section 4, we have addressed the Federal governmentwide transition from the requirement to register in *SAM.gov* the Data Universal Numbering System number (DUNS) to the implementation of the Unique Entity Identifier (UEI). In other sections, references to DUNS have been replaced with references to UEI. In section 5(b), we have revised the instructions for submission of paper applications, including by providing that requests to submit a paper application may be made by email and updating the mailing address for the submission of paper applications. We have also made some technical updates to the instructions.

The revised common instructions are set forth as follows:

Common Set of Instructions for Applicants

Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package from the Department's website or *Grants.gov*.

To obtain a copy via the Department's website, use the following address: *www.ed.gov/fund/grant/apply/grantapps/index.html.*

2. *Content and Form of Application Submission:* Requirements concerning the content and form of an application, together with the forms you must submit, are in the application package for the program.

3. *Submission Dates and Times:* Submit applications for grants under the program electronically using *Grants.gov*. For information (including dates and times) about how to submit your application electronically, please refer to *Other Submission Requirements* in section 5 of these instructions.

We do not consider an application that does not comply with the deadline requirements.

4. *Unique Entity Identifier, Taxpayer Identification Number, and System for Award Management:* To do business with the Department, and to submit your application electronically using *Grants.gov*, you must—

a. Have a Unique Entity Identifier (UEI) and a Taxpayer Identification Number (TIN);

b. Be registered in the System for Award Management (*SAM.gov*), the Government's primary registrant database;

c. Provide your UEI number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

Until April 3, 2022, entities that are *not already registered* in *SAM.gov* and who wish to do business with the Federal Government must obtain and/or use a valid Data Universal Numbering System (DUNS) number to register their entity in *SAM.gov*. On and after April 4, 2022, entities that are not registered in *SAM.gov* will be assigned a UEI when they register and will not need to use a DUNS for entity registration or reporting. If registering before April 4, 2022, you can obtain a DUNS number from Dun and Bradstreet at the following website: *http://fedgov.dnb.com/webform.* A DUNS number can be created within one to two business days. To register in *SAM.gov*, click on the ''Get Started'' link under the ''Register Your Entity. . .'' heading in *SAM.gov*.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service (IRS). If you are an individual, you can obtain a TIN from the IRS or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process usually takes approximately 7 to 10 business days, but can take longer, depending on the completeness and accuracy of the data you enter into the *SAM.gov* database. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number, if applying prior to April 4, 2022, and TIN. If registering in *SAM.gov* on or after April 4, 2022, *SAM.gov* will issue you a UEI at the time you complete the registration process. We recommend that you register early. If you are unable to submit an application on *Grants.gov* by the application deadline because you do not have an active SAM registration, you will not be considered for funding.

Note: Once your *SAM.gov* registration is active, it may be 24 to 48 hours before you can access the information in, and submit an application through, *Grants.gov*.

If you are currently registered with *SAM.gov*, you may not need to make any changes. However, please make certain that the TIN associated with your UEI is correct if you register on or after April 4, 2022. If you register with a DUNS before April 4, 2022, please make certain that the TIN associated with your DUNS is correct.

Note: You must update your SAM registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov*. To further assist you with registering in *SAM.gov* or updating your existing SAM registration, see the Quick Start Guide for Grant Registrations and the Entity Registration Video at *https://sam.gov/content/entity-registration.*

In addition, in order to submit your application via *Grants.gov*, you must (1) register as an applicant using your UEI number and (2) be designated by your organization's E-Biz Point of Contact as an Authorized Organization Representative (AOR). Details on these steps are outlined at the following *Grants.gov* web page: *https://www.grants.gov/web/grants/register.html.*

5. *Other Submission Requirements:*

a. *Electronic Submission of Applications.*

We are participating as a partner in the Government-wide *Grants.gov* site. Submit applications electronically using *Grants.gov* and do not email them unless explicitly allowed in a competition NIA.

You may access the electronic grant applications at *www.grants.gov.* You must search for the downloadable application package for this competition by the Assistance Listing Number (ALN). Do not include the ALN's alpha suffix in your search (*e.g.,* search for 84.184, not 84.184D).

A *Grants.gov* applicant must apply online using Workspace, a shared environment in *Grants.gov* where members of a grant team may simultaneously access and edit different web forms within an application. An applicant can create an individual Workspace for each application and establish for that application a collaborative application package that allows more than one person in the applicant's organization to work concurrently on an application. The *Grants.gov* system also enables the applicant to reuse forms from previous submissions, check forms in and out to complete them, and submit the application package. For access to further instructions on how to apply using *Grants.gov,* refer to: *www.grants.gov/web/grants/applicants/apply-for-grants.html.*

Please note the following:

• Applicants needing assistance with *Grants.gov* may contact the *Grants.gov* Support Center either by calling 1–800–518–4726 or by sending an email to *support@grants.gov.* The *Grants.gov* Support Center is available 24 hours a day, seven days a week, except for Federal holidays. Applicants needing assistance from Principal Office staff with their applications should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section in the competition NIA during normal business hours and no later than 5:00 p.m., Eastern Time, on the application deadline date.

• The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your internet connection. Therefore, we recommend that you leave yourself plenty of time to complete your submission.

• Applications received by *Grants.gov* are date- and time-stamped upon submission. Your application must be fully uploaded and submitted and must be date- and time-stamped by the *Grants.gov* system no later than 11:59:59 p.m., Eastern Time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date- and time-stamped by the *Grants.gov* system—after 11:59:59 p.m., Eastern Time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from *Grants.gov,* we will notify you if we are rejecting your application because it was late. Receipt of a date- and time-stamp does not mean that your application meets program eligibility requirements described in the application package.

• You should review and follow the Education Submission Procedures for submitting an application through *Grants.gov* that are included in the application package for the program to ensure that you submit your application on time. You can also find the Education Submission Procedures pertaining to *Grants.gov* under News and Events on the Department's G5 system home page at *www.G5.gov.* In addition, for specific guidance and procedures for submitting an application through *Grants.gov,* please refer to the *Grants.gov* website at: *www.grants.gov/web/grants/applicants/apply-for-grants.html.*

• When you submit your application electronically, all documents must be submitted electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all Department-specific assurances and certifications.

• When you submit your application electronically, you must upload any narrative sections and all other attachments to your application as files in either Portable Document Format (PDF) or Microsoft Word. Although applicants have the option of uploading any narrative sections and all other attachments to their application in either PDF or Microsoft Word, we recommend applicants submit all documents as read-only flattened PDFs, meaning any fillable PDF files must be saved and submitted as non-fillable PDF files and not as interactive or fillable PDF files, to better ensure applications are processed in a more timely, accurate, and efficient manner. If you choose to submit your application in Microsoft Word, you may do so using any version of Microsoft Word (*i.e.,* a document ending in a .doc or .docx extension). If you upload a file type other than PDF or Microsoft Word or if you submit a password-protected file, we will be unable to review that material. Please note that this will likely result in your application not being considered for funding. The Department will not convert material from other formats to PDF or Microsoft Word.

• After you electronically submit your application, you will receive from *Grants.gov* an automatic notification of receipt that contains a *Grants.gov* tracking number. *Grants.gov* also will notify you automatically by email if your application met all of the *Grants.gov* validation requirements or if there were any errors (such as submission of your application by someone other than a registered AOR, issues with your UEI number, or inclusion of an attachment with a file name that contains special characters). You will be given an opportunity to correct any errors and resubmit, but you must still meet the deadline for submission of your application.

Once your application is successfully validated by *Grants.gov* the Department will retrieve your application from *Grants.gov* and send you an email with a unique PR/Award number for your application.

Email confirmations and receipts from *Grants.gov* do not indicate receipt by the Department, nor do they mean that your application is complete or has met all application requirements. While your application may have been successfully validated by *Grants.gov,* it also must be reviewed in accordance with the Department's application requirements as specified in the competition NIA and in these application instructions. It is your responsibility to ensure that your submitted application has met all of the Department's requirements. Additionally, we may request that you provide us with original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you experience problems submitting your application through *Grants.gov,* please contact the *Grants.gov* Support Desk immediately, toll-free, at 1–800–518–4726. The *Grants.gov* Support Center will provide you with a Support Desk Case Number documenting your communication. You must retain your Support Desk Case Number for future reference as proof of your communication with the Support Center. Please subsequently contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section in the competition NIA and provide an explanation of the technical problem you experienced with *Grants.gov,* along with the *Grants.gov* Support Desk Case Number.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems within the *Grants.gov* system, we will grant you an extension until 11:59:59 p.m., Eastern Time, the following

business day to enable you to transmit your application electronically, provided we can verify the technical issues that affected your ability to submit your application on time via your *Grants.gov* Support Desk Case Number.

Note: The extensions to which we refer in this section apply only to technical problems with the *Grants.gov* system. We will not grant you an extension if you failed to fully register in order to submit your application to *Grants.gov* (including with the required UEI number and TIN currently registered in SAM) before the application deadline date and time or if the technical problem you experienced is unrelated to the *Grants.gov* system.

b. *Submission of Paper Applications.*

We discourage paper applications, but if electronic submission is not possible (*e.g.,* you do not have access to the internet), (1) you must provide a prior written notification that you intend to submit a paper application and (2) your paper application must be postmarked by the application deadline date.

The prior written notification may be submitted by email or by mail to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of the competition NIA. If you submit your notification by email, it must be received by the Department no later than 14 calendar days before the application deadline date. If you mail your notification to the Department, it must be postmarked no later than 14 calendar days before the application deadline date.

If you submit a paper application, you must have, and include on your application, a UEI number and mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, OFO/G5 Functional Application Team, Mail Stop 5C231, Attention: (Assistance Listing Number + Suffix Letter), 400 Maryland Avenue SW, Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

We will not consider applications postmarked after the application deadline date.

Note for Mail Delivery of Paper Applications: If you mail your application to the Department—

(1) You must indicate on the envelope and in Item 11 of the SF 424 the ALN, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The G5 Functional Application Team will notify you of the Department's receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of the competition NIA.

Accommodations; Accessible Format: Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section in the competition NIA. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in the competition NIA.

On request to the 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, 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 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.

Roberto J. Rodriguez,

Assistant Secretary for Planning, Evaluation and Policy Development.

[FR Doc. 2021–27979 Filed 12–23–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Request for Information: DOE's Cybersecurity Capability Maturity Model (C2M2) Version 2.0 (July 2021); Extension

AGENCY: Office of Cybersecurity, Energy Security, and Emergency Response; Department of Energy.

ACTION: Extension of public comment period.

SUMMARY: The U.S. Department of Energy (DOE) is extending the public comment period for its Request for Information (RFI) regarding the Cybersecurity Capability Maturity Model (C2M2). DOE published the RFI in the **Federal Register** on November 24, 2021, establishing a 30-day public comment period that ends December 27, 2021. DOE is extending the public comment period for 45 days to February 10, 2022.

DATES: The comment period for the RFI published on November 24, 2021 (86 FR 67038) is extended. DOE will accept responses regarding this RFI received no later than February 10, 2022.

ADDRESSES: To access and review the Cybersecurity Capability Maturity Model (C2M2), visit *www.energy.gov/c2m2.*

Comments should be submitted by email to *C2M2@hq.doe.gov* using the Comment Submission Form available here: *https://energy.gov/sites/default/files/2021-11/Comment%20Submission%20Form%20-%20Cybersecurity%20Capability%20Maturity%20Model%20%28C2M2%29.docx.* Use the email subject line: ''C2M2 Public Comment from [name/organization].''

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including postal mail and hand delivery/courier, the Department has found it necessary to make temporary modifications to the comment submission process in light of the ongoing coronavirus 2019 (''COVID–19'') pandemic. DOE is currently suspending receipt of public comments via postal mail and hand delivery/courier. If a commenter finds that this

change poses an undue hardship, please contact CESER staff at (202) 586–3057 to discuss the need for alternative arrangements. Once the COVID–19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier.

FOR FURTHER INFORMATION CONTACT: Mr. Fowad Muneer, Acting Deputy Assistant Secretary for the Cybersecurity for Energy Delivery Systems Division, U.S. Department of Energy, Office of Cybersecurity, Energy Security, and Emergency Response. Tel.: (202) 586–5961. Email: *fowad.muneer@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: On November 24, 2021, DOE published a notice of RFI to solicit public comment on Version 2.0 of the C2M2, a tool that helps organizations evaluate and improve their cybersecurity capabilities, considering their specific risk environment. DOE released Version 2.0 in July 2021, and the update was guided by input from the Energy Sector C2M2 Working Group, which comprises 145 energy sector cybersecurity practitioners representing 77 energy sector and cybersecurity organizations. Version 2.0 updates the model from Version 1.1, released in 2014, and includes a variety of updates to the model domains and practices to better address emerging technologies and the evolving cyber threat landscape.

To obtain the broadest possible input, DOE seeks public comment on the C2M2 to inform the C2M2 Working Group as it develops future model updates. DOE believes it is appropriate to extend the public comment period to allow additional time for interested parties to submit comments. Therefore, DOE is extending the deadline for response until February 10, 2022, to provide interested parties additional time to prepare and submit responses.

Specifically, DOE seeks input on the following items:

- The usefulness of C2M2 practices in evaluating and improving cybersecurity program capabilities.
- The applicability of practice language to the IT and OT environments in use by energy sector organizations.
- The readability of and ability to understand practice language.
- The completeness of cybersecurity domains, objectives, and practices included within the C2M2.
- The effectiveness of guidance documentation (*e.g.,* model introduction sections, domain introductions, and appendices) in conveying model concepts, architecture, and how to use the model.
- Any other potential improvements to the C2M2 documentation or practices contained therein.

For more information on the C2M2, or to review the model document, visit *www.energy.gov/c2m2.*

Confidential Business Information: Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email two well-marked copies: One copy of the document marked ''confidential'' including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Signing Authority

This document of the Department of Energy was signed on December 21, 2021, by Fowad Muneer, Acting Deputy Assistant Secretary for the Cybersecurity for Energy Delivery Systems Division, 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 December 22, 2021.

Treena V. Garrett,

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

[FR Doc. 2021–28148 Filed 12–23–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Notice of Availability of Guidance and Application for Hydroelectric Incentive Program

AGENCY: Water Power Technologies Office, Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of availability of guidance and open application period.

SUMMARY: The U.S. Department of Energy (DOE) gives notice of updated guidance for the Energy Policy Act of 2005 program. The guidance describes the hydroelectric incentive payment requirements and explains the type of information that owners or authorized operators of qualified hydroelectric facilities must provide DOE when applying for hydroelectric incentive payments. The hydroelectric incentive payments are a benefit available for electric energy generated and sold for a specified 10-year period as authorized under the Energy Policy Act of 2005. In Congressional appropriations for Federal fiscal year 2021, DOE received funds to support this hydroelectric incentive program. At this time, DOE is only accepting applications from owners and authorized operators of qualified hydroelectric facilities for hydroelectricity generated and sold in calendar year 2020.

DATES: DOE is currently accepting applications from December 27, 2021 through February 10, 2022. Applications must be sent to *hydroincentive@ee.doe.gov* by midnight EDT, February 10, 2022, or they will not be considered timely filed for calendar year 2020 incentive payments.

ADDRESSES: Interested parties are to submit applications electronically to *hydroincentive@ee.doe.gov.* DOE's December 2021 Guidance is available at: *https://www.energy.gov/eere/water/water-power-funding-opportunities.*

FOR FURTHER INFORMATION CONTACT: Questions may be addressed to Mr. Corey Vezina, U.S. Department of Energy, Golden Field Office, 15013 Denver West Parkway, Golden, CO 80401, (240) 562–1382 or by email at *hydroincentive@ee.doe.gov.* Further instruction can be found in the December 2021 Guidance posted at *https://www.energy.gov/eere/water/water-power-funding-opportunities. Electronic communications are recommended for correspondence and required for submission of application information.*

SUPPLEMENTARY INFORMATION: In section 242 of the Energy Policy Act of 2005 (EPAct 2005; Pub. L. 109–58), as amended by section 3005(a) of the Energy Act of 2020 (Energy Act 2020; Pub. L. 116–260), Congress established a program to support the expansion of hydropower energy development at existing dams and impoundments through an incentive payment procedure for eligible facilities (section 242), codified at 42 U.S.C. 15881. Congress amended section 242 in the Energy Act of 2020 (Pub. L. 116–260) by expanding the eligibility window and amending the definition of a qualified hydroelectric facility. The Infrastructure

Investment and Jobs Act of 2021 (Pub. L. 117–58) made further amendments to section 242.

Section 242 directs the Secretary to provide incentive payments to the owners or authorized operators of hydroelectric generation facilities in accordance with specific statutory instructions. The Secretary is directed to issue incentive payments, subject to the availability of appropriations, for hydroelectric energy generated and sold by a qualified hydroelectric facility during the incentive period. Incentive payments may only be made upon receipt by the Secretary of an incentive payment application that demonstrates that the applicant is eligible to receive such payment and satisfies other requirements as the Secretary deems necessary (42 U.S.C. 15881(a)) In FY 2021, Congress appropriated to DOE $7,000,000 for this purpose.

The Secretary may only issue payments for the electric energy generated and sold by a qualified hydroelectric facility that began operations during the period of 22 fiscal years beginning after the first fiscal year occurring after the program's enactment, August 8, 2005 (42 U.S.C. 15881(c)). A qualified hydroelectric facility may receive payments for a period of 10 consecutive fiscal years, known as the incentive period, which begins with the fiscal year that electric energy generated from the facility is first eligible for such payments (42 U.S.C. 15881(d)). Payments made by the Secretary are to be based on the number of kilowatt hours of hydroelectric energy generated by the facility during the incentive period. The amount of such payment shall be 1.8 cents per kilowatt hour (as adjusted by the Internal Revenue Code of 1986), subject to the availability of appropriations, except that no facility may receive more than $1,000,000 in one calendar year (42 U.S.C. 15881(e)). No payments will be made after the expiration of the period of 32 fiscal years beginning with the first full fiscal year occurring after August 8, 2005, and no payment may be made under this section to any such facility after a payment has been made with respect to such facility for a period of 10 fiscal years (42 U.S.C. 15881(f)). The Secretary is authorized to carry out the purposes of this program for each of the fiscal years of 2021 through 2036 (42 U.S.C. 15881(g)).

In section 242, Congress defines a qualified hydroelectric facility to mean ''a turbine or other generating device owned or solely operated by a non-Federal entity—(A) that generates hydroelectric energy for sale; and (B)(i) that is added to an existing dam or conduit; or (ii)(I) that has generating capacity of not more than 20 megawatts; (II) for which the non-Federal entity has received a construction authorization from the Federal Energy Regulatory Commission, if applicable; and (III) that is constructed in an area in which there is inadequate electric service, as determined by the Secretary, including by taking into consideration—(aa) access to the electric grid; (bb) the frequency of electric outages; or (cc) the affordability of electricity'' (42 U.S.C. 15881(b)(1)).

Additionally, Congress defined an existing dam or conduit to mean any dam or conduit constructed and completed before August 8, 2005 and does not require any construction or enlargement of impoundment or diversion structures, other than repair or reconstruction, in connection with the installation of a turbine or other generating device (42 U.S.C. 15881(b)(2)). The term conduit maintains the same meaning here as when used in section 30(a)(2) of the Federal Power Act (16 U.S.C. 823a(a)(3)(A)) (42 U.S.C. 15881(b)(3)).

Further, these defined terms apply without regard to the hydroelectric kilowatt capacity of the facility, without regard to whether the facility uses a dam owned by a governmental or nongovernmental entity, and without regard to whether the facility begins operation on or after the date August 8, 2005 (42 U.S.C. 15881(b)).

Recently DOE made updates to clarify its Guidance for the Energy Policy Act of 2005 section 242 program. The December 2021 Guidance is available at: *https://www.energy.gov/eere/water/water-power-funding-opportunities.* Each application will be reviewed based on the Guidance. The updates made to the Guidance involve edits to clarify the definition of existing and new terms, eligibility window and incentive period, incentive payment calculations, application content requirements, and the duration of payments available to generation facilities.

DOE notes that applicants that received incentive payments for prior calendar years must submit a new and complete application addressing all eligibility requirements for hydroelectricity generated and sold in calendar year 2020. DOE will not consider previously submitted application materials. Applications that refer to previous application materials or statements in lieu of submitting current information will not be considered. As authorized under section 242 of EPAct 2005, and as explained in the Guidance, DOE also notes that it will only accept applications from qualified hydroelectric facilities that began operations at an existing dam or conduit between October 1, 2005, and September 30, 2027.

When submitting information to DOE for the section 242 program, it is recommended that applicants carefully read and review the completed content of the Guidance for this process. When reviewing applications, DOE may corroborate the information provided with information that DOE finds through FERC e-filings, contact with power off-taker, and other due diligence measure carried out by reviewing officials. DOE may require the applicant to conduct and submit an independent audit at its own expense, or DOE may conduct an audit to verify the number of kilowatt-hours claimed to have been generated and sold by the qualified hydroelectric facility and for which an incentive payment has been requested or made.

Signing Authority

This document of the Department of Energy was signed on December 15, 2021, by Jennifer Garson, Acting Director, Water Power Technologies Office, 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 December 20, 2021.

Treena V. Garrett,

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

[FR Doc. 2021–27915 Filed 12–23–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Request for Information (RFI) on Using a Consent-Based Siting Process To Identify Federal Interim Storage Facilities; Correction

AGENCY: Office of Spent Fuel and Waste Disposition, Office of Nuclear Energy, Department of Energy.

ACTION: Request for information; correction.

SUMMARY: On December 1, 2021, the Office of Nuclear Energy, Department of Energy, published a request for information in the **Federal Register** on how to site federal facilities for the temporary, consolidated storage of spent nuclear fuel using a consent-based approach. This document corrects broken hyperlinks to the Invitation for Public Comment and to the 2017 Draft Consent-Based Siting Process for Consolidated Storage and Disposal Facilities for Spent Nuclear Fuel and High-Level Radioactive Waste.

FOR FURTHER INFORMATION CONTACT: Please send any questions to *consentbasedsiting@hq.doe.gov,* or to Alisa Trunzo at 301–903–9600.

Correction

In the **Federal Register** of December 1, 2021, FR Doc. 2021–25724, (86 FR 68244) under the **SUPPLEMENTARY INFORMATION** section, the following corrections are made:

(1) First column, first paragraph, lines 9 thru 11, the weblink is corrected as follows:

https://www.energy.gov/sites/prod/files/2016/12/f34/Summary%20of%20Public%20Input%20Report%20FINAL.pdf.

(2) First column, first paragraph, lines 22 thru 25, the weblink is corrected as follows:

https://www.energy.gov/sites/prod/files/2017/01/f34/Draft%20Consent-Based%20Siting%20Process%20and%20Siting%20Considerations.pdf.

(3) First column, fourth paragraph, under the heading, Questions for Input, lines 9 thru 11, the weblink is corrected as follows:

https://www.energy.gov/sites/prod/files/2017/01/f34/Draft%20Consent-Based%20Siting%20Process%20and%20Siting%20Considerations.pdf.

(4) Second column, under the heading, Area 1: Consent-Based Siting Process, paragraph 7, the weblink is corrected as follows:

https://www.energy.gov/sites/prod/files/2017/01/f34/Draft%20Consent-Based%20Siting%20Process%20and%20Siting%20Considerations.pdf.

Reason for Correction: The change aims to fix the standard hyperlink format accepted by the FRN template.

Signing Authority

This document of the Department of Energy was signed on December 15, 2021, by Dr. Kathryn Huff, Principal Deputy Assistant Secretary for the Office of Nuclear 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 December 21, 2021.

Treena V. Garrett,

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

[FR Doc. 2021–28009 Filed 12–23–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

National Nuclear Security Administration

Exports of U.S.-Origin Highly Enriched Uranium (HEU) for Medical Isotope Production: Certification of Sufficient Supplies of Non-HEU-based Molybdenum-99 (Mo-99) To Meet Needs of Patients in the United States

AGENCY: National Nuclear Security Administration (NNSA), Department of Energy (DOE).

ACTION: Notice.

SUMMARY: DOE and Department of Health and Human Services (HHS), in accordance with the American Medical Isotopes Production Act of 2012 (AMIPA), have issued a joint Secretarial certification that there is a sufficient global supply of Mo-99 produced without the use of HEU available to meet the needs of patients in the United States and that it is not necessary to export United States-origin HEU for the purposes of medical isotope production in order to meet United States patient needs. This certification is effective as of January 2, 2022.

FOR FURTHER INFORMATION CONTACT: Requests for additional information may be sent to Max Postman in the Office of Conversion *OfficeofConversion@nnsa.doe.gov* or 202–586–9114.

SUPPLEMENTARY INFORMATION:

Authority and Background:

The American Medical Isotopes Production Act of 2012 (AMIPA) (subtitle F, Title XXXI of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–139)), enacted on January 2, 2013, amended section 134 of the Atomic Energy Act of 1954 (42 U.S.C. 2160d) by striking subsection c. and inserting language that prohibits the Nuclear Regulatory Commission (NRC) from issuing a license for the export of HEU from the United States for the purposes of medical isotope production, effective seven years after enactment of AMIPA, subject to a certification regarding the sufficiency of Mo-99 supply in the United States.

AMIPA requires the Secretary of Energy to either jointly certify, with the Secretary of Health and Human Services, that there is a sufficient supply of Mo-99 produced without the use of HEU available to meet U.S. patient needs, and that it is not necessary to export U.S.-origin HEU for the purposes of medical isotope production in order to meet U.S. patient needs, or to unilaterally certify that there is insufficient supply of Mo-99 produced without the use of HEU available to satisfy the domestic market and that the export of U.S.-origin HEU for the purposes of medical isotope production is the most effective temporary means to increase the supply of Mo-99 to the domestic U.S. market, thereby delaying the enactment of the export license ban for up to six years.

DOE published a **Federal Register** notice (85 FR 3362) on January 21, 2020 certifying that, at the time, there was an insufficient global supply of Mo-99 produced without the use of HEU and that the export of U.S.-origin HEU for the purposes of medical isotope production was the most effective temporary means to increase the supply of Mo-99 to the domestic U.S. market. This certification was effective for no more than two years from the effective date of January 2, 2020. The **Federal Register** notice stated that DOE would conduct periodic reviews of the domestic U.S. and global Mo-99 market and would work toward a certification to Congress, regarding the sufficiency of supply as soon as the statutory conditions are satisfied.

Based on an expert third party market analysis, as well as the assessment of subject matter experts in both agencies, the Secretary of Energy and the Secretary of Health and Human Services have jointly certified that there is a sufficient global supply of Mo-99 produced without the use of HEU available to meet the needs of patients in the United States. Furthermore, while there is the potential for future shortages of other medical isotopes, including iodine-131 and xenon-133, the export of HEU would not mitigate these risks. Therefore, the Secretaries also have jointly certified that it is not necessary to export United States-origin HEU for the purposes of medical isotope production in order to meet United States patient needs.

This joint certification reflects DOE's progress in working with international partners to convert medical isotope production facilities to the use of low enriched uranium (LEU) and in supporting the establishment of domestic supplies of Mo-99 produced without use of HEU. Three of the four major global producers now produce Mo-99 using LEU. The other major producer still relies partially on HEU but is on track to convert to LEU-based processes in 2022. The Department of Health and Human Services has also played a critical role in achieving this milestone, including approval of LEU Mo-99 technologies and through the 2018 approval of a New Drug Application for the first domestic production of Mo-99 in nearly 30 years.

The global market is now capable of producing enough Mo-99 using LEU to meet U.S. demand, but ongoing engagement between producers, radiopharmaceutical companies, and other private sector stakeholders will be needed to ensure that U.S. patient needs continue to be met. Mo-99 producers must continue to coordinate regarding the security of global supply and must maintain the ability to ramp up production where needed to compensate for shortfalls from other producers and maintain accessibility of Mo-99 through the supply chain. DOE will reinforce this message through its ongoing engagements with the Mo-99 community.

Signing Authority

This document of the Department of Energy was signed on December 8, 2021, by Corey Hinderstein, Deputy Administrator for Defense Nuclear Nonproliferation, 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 December 21, 2021.

Treena V. Garrett,

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

[FR Doc. 2021–28017 Filed 12–23–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1888–038]

York Haven Power Company, LLC; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for a temporary variance from flow requirements for the York Haven Hydroelectric Project, located on the Susquehanna River in Dauphin, Lancaster, and York counties, Pennsylvania, and has prepared an Environmental Assessment (EA) for the project. The project does not occupy Federal lands.

The EA contains the staff's analysis of the potential environmental effects of the temporary variance and concludes that licensing the variance would not constitute a major federal action that would significantly affect the quality of the human environment.

The EA may be viewed on the Commission's website at *http://www.ferc.gov* using the ''elibrary'' link. Enter the docket number (P–1888) in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3372, or for TTY, (202) 502–8659.

All comments must be filed within 30 days from the date of this notice. The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp*. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp*. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–1888–038.

For further information, contact Alicia Burtner at (202) 502–8038 or *Alicia.Burtner@ferc.gov.*

Dated: December 20, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–28025 Filed 12–23–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP22–29–000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on December 8, 2021, Columbia Gas Transmission, LLC (Columbia), 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700, filed in the above referenced docket a prior notice pursuant to sections 157.205 and 157.216(b) of the Commission's regulations under the Natural Gas Act (NGA) and its blanket certificate issued in Docket No. CP83–76–000 requesting authorization to abandon 11 injection/withdrawal wells, 12 associated storage pipelines, and appurtenances at its Holmes and Wayne Storage Field in Holmes and Wayne Counties, Ohio. Columbia states that these wells provide little value with each contributing a de minimis amount to the total deliverability of the storage field and plugging and abandoning each well will reduce integrity risk. Columbia also seeks to abandon 0.99 miles of storage lines in place and 0.14 miles of storage lines by removal; Columbia will no longer have a use for these lines once the wells are abandoned. Columbia estimates the cost of the project to be approximately $7 million. Columbia avers that the proposed abandonment will have no impact on its existing customers or affect its existing storage operations. Columbia states that there will be no change its the existing boundary, total inventory, reservoir pressure, reservoir and buffer boundaries, or certificated capacity of the Holmes and Wayne Storage Field as a result of the proposed abandonment, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

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://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions concerning this application should be directed to David Alonzo, Manager, Project Authorizations, Columbia Gas Transmission, LLC, 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700, by phone at (832) 320–5477 or by email at *david_alonzo@tcenergy.com.*

Public Participation

There are three ways to become involved in the Commission's review of this project: You can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on February 18, 2022. How to file protests, motions to intervene, and comments is explained below.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[1] any person [2] or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,[3] and must be submitted by the protest deadline, which is February 18, 2022. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [4] and the regulations under the NGA [5] by the intervention deadline for the project, which is February 18, 2022. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before February 18, 2022. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How to File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP22–29–000 in your submission. The Commission encourages electronic filing of submissions.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov)* under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Protest'', ''Intervention'', or ''Comment on a Filing.''

The Commission's eFiling staff are available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

(2) You can file a paper copy of your submission. Your submission must reference the Project docket number CP22–29–000.

To mail via USPS, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To mail via any other courier, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at: *david_alonzo@tcenergy.com,* 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all

[1] 18 CFR 157.205.

[2] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[3] 18 CFR 157.205(e).

[4] 18 CFR 385.214.

[5] 18 CFR 157.10.

formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: December 20, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–28024 Filed 12–23–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC22–25–000.

Applicants: Chambers Cogeneration Limited Partnership, Carneys Point Generation II, L.L.C.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Chambers Cogeneration Limited Partnership, et al.

Filed Date: 12/17/21.

Accession Number: 20211217–5417.

Comment Date: 5 p.m. ET 1/7/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–3461–001; ER11–4443–004; ER16–1689–003.

Applicants: ArcelorMittal Cleveland LLC, AK Electric Supply, LLC, ArcelorMittal USA, LLC.

Description: Notice of Non-Material Change in Status of AK Electric Supply, LLC, et al.

Filed Date: 12/15/21.

Accession Number: 20211215–5311.

Comment Date: 5 p.m. ET 1/5/22.

Docket Numbers: ER11–4443–005.

Applicants: AK Electric Supply, LLC.

Description: Notice of Non-Material Change in Status of AK Electric Supply LLC.

Filed Date: 12/15/21.

Accession Number: 20211215–5312.

Comment Date: 5 p.m. ET 1/5/22.

Docket Numbers: ER17–2515–006.

Applicants: Chambers Cogeneration, Limited Partnership.

Description: Compliance filing: Informational Filing Pursuant to Schedule 2 to be effective N/A.

Filed Date: 12/20/21.

Accession Number: 20211220–5124.

Comment Date: 5 p.m. ET 1/10/22.

Docket Numbers: ER17–998–002.

Applicants: DATC Path 15, LLC.

Description: Compliance filing: Compliance to 3000014 to be effective 4/21/2017.

Filed Date: 12/20/21.

Accession Number: 20211220–5161.

Comment Date: 5 p.m. ET 1/10/22.

Docket Numbers: ER21–1702–001.

Applicants: ISO New England Inc., Central Maine Power Company.

Description: Compliance filing: ISO New England Inc. submits tariff filing per 35: Central Maine Power; ER21–17025—Supplemental Order No. 864 Compliance Filing to be effective 1/1/2020.

Filed Date: 12/20/21.

Accession Number: 20211220–5160.

Comment Date: 5 p.m. ET 1/10/22.

Docket Numbers: ER22–42–001.

Applicants: DTE Electric Company.

Description: Tariff Amendment: Deficiency Filing in Docket ER22–42–000 to be effective 7/1/2021.

Filed Date: 12/20/21.

Accession Number: 20211220–5163.

Comment Date: 5 p.m. ET 1/10/22.

Docket Numbers: ER22–205–001.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: Tariff Amendment: Errata to Notice of Cancellation of Rate Schedule No. 263 to be effective 12/27/2021.

Filed Date: 12/20/21.

Accession Number: 20211220–5125.

Comment Date: 5 p.m. ET 1/10/22.

Docket Numbers: ER22–683–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3868 Southwestern Power Admin/SpringfieldMO Utilities Int Ag to be effective 1/1/2022.

Filed Date: 12/17/21.

Accession Number: 20211217–5316.

Comment Date: 5 p.m. ET 1/7/22.

Docket Numbers: ER22–684–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Attachment AE Revisions to Add Hybrid Storage Market Resource Provisions to be effective 2/19/2022.

Filed Date: 12/20/21.

Accession Number: 20211220–5021.

Comment Date: 5 p.m. ET 1/10/22.

Docket Numbers: ER22–685–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original NSA, SA No. 6265; Queue No. M04 to be effective 11/19/2021.

Filed Date: 12/20/21.

Accession Number: 20211220–5180.

Comment Date: 5 p.m. ET 1/10/22.

Docket Numbers: ER22–686–000.

Applicants: Entergy Arkansas, LLC.

Description: § 205(d) Rate Filing: EAL MBR Tariff Compliance to be effective 9/1/2021.

Filed Date: 12/20/21.

Accession Number: 20211220–5190.

Comment Date: 5 p.m. ET 1/10/22.

Docket Numbers: ER22–687–000.

Applicants: Entergy Mississippi, LLC.

Description: § 205(d) Rate Filing: EML MBR Tariff Compliance to be effective 9/1/2021.

Filed Date: 12/20/21.

Accession Number: 20211220–5191.

Comment Date: 5 p.m. ET 1/10/22.

Docket Numbers: ER22–688–000.

Applicants: AR Searcy Project Company, LLC.

Description: § 205(d) Rate Filing: MBR Tariff Compliance to be effective 9/1/2021.

Filed Date: 12/20/21.

Accession Number: 20211220–5192.

Comment Date: 5 p.m. ET 1/10/22.

Docket Numbers: ER22–689–000.

Applicants: MS Sunflower Project Company, LLC.

Description: § 205(d) Rate Filing: MBR Tariff Compliance to be effective 9/1/2021.

Filed Date: 12/20/21.

Accession Number: 20211220–5194.

Comment Date: 5 p.m. ET 1/10/22.

Docket Numbers: ER22–691–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original NSA, SA No. 6266; Queue No. AB2–175 to be effective 11/19/2021.

Filed Date: 12/20/21.

Accession Number: 20211220–5201.

Comment Date: 5 p.m. ET 1/10/22.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES22–18–000.

Applicants: Portland General Electric Company.

Description: Amendment to Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Portland General Electric Company.

Filed Date: 12/17/21.

Accession Number: 20211217–5402.

Comment Date: 5 p.m. ET 1/3/22.

Docket Numbers: ES22–24–000.

Applicants: Consumers Energy Company.

Description: Application Under Section 204 of the Federal Power Act for

Authorization to Issue Securities of Consumers Energy Company.

Filed Date: 12/17/21.

Accession Number: 20211217–5406.

Comment Date: 5 p.m. ET 1/7/22.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RD22–1–000.

Applicants: North American Electric Reliability Corporation.

Description: Petition of North American Electric Reliability Corporation and SERC Reliability Corporation for Approval of Proposed Regional Reliability Standard PRC–006–SERC–03 and Request for Expedited Action.

Filed Date: 12/14/21.

Accession Number: 20211214–5283.

Comment Date: 5 p.m. ET 1/19/22.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 20, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–28023 Filed 12–23–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 10198–031]

City of Pelican, Pelican Utility District; Notice of Intent To File License Application, Filing of Pre-Application Document, Approving Use of the Traditional Licensing Process

a. *Type of Filing:* Notice of Intent to File License Application and Request to Use the Traditional Licensing Process.

b. *Project No.:* 10198–031.

c. *Date Filed:* September 27, 2021 (Notice of Intent); November 12, 2021 (Pre-Application Document and Request to Use the TLP).

d. *Submitted By:* City of Pelican, Pelican Utility District.

e. *Name of Project:* Pelican Hydroelectric Project.

f. *Location:* On the Pelican Creek in the City of Pelican, Alaska. No federal lands are occupied by the project.

g. *Filed Pursuant to:* 18 CFR 5.3 of the Commission's regulations.

h. *Potential Applicant Contact:* Patricia Phillips, Mayor, City of Pelican, Box 737 Pelican, AK 99832; (907) 735–2202; *mayorphillips@pelicancity.org.*

i. *FERC Contact:* Ingrid Brofman at (202) 502–8347; or email at *ingrid.brofman@ferc.gov.*

j. Pelican Utility District filed its request to use the Traditional Licensing Process on November 12, 2021. Pelican Utility District provided public notice of its request on November 14, 2021. In a letter dated December 20, 2021, the Director of the Division of Hydropower Licensing approved Pelican Utility District's request to use the Traditional Licensing Process.

k. With this notice, we are initiating informal consultation with the U.S. Fish and Wildlife Service and NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR, Part 402; and NOAA Fisheries under section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act and implementing regulations at 50 CFR 600.920. We are also initiating consultation with the Alaska State Historic Preservation Officer, as required by section 106, National Historic Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating the City of Pelican, Pelican Utility District as the Commission's non-federal representative for carrying out informal consultation pursuant to section 7 of the Endangered Species Act and section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act; and consultation pursuant to section 106 of the National Historic Preservation Act.

m. Pelican Utility District filed a Pre-Application Document (PAD; including a proposed process plan and schedule) with the Commission, pursuant to 18 CFR 5.6 of the Commission's regulations.

n. A copy of the PAD may be viewed and/or printed on the Commission's website (*http://www.ferc.gov*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY).

o. The licensee states its unequivocal intent to submit an application for a new license for Project No. 10198. Pursuant to 18 CFR 16.8, 16.9, and 16.10, each application for a new license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license. All applications for license for this project must be filed by September 16, 2024.

p. Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filing and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–28029 Filed 12–23–21; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA HQ–OAR–2020–0624; FRL–9387–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''NESHAP for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills (Renewal)'' (EPA ICR Number 1805.11, OMB Control Number 2060–0377), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through December 31, 2021. Public comments were previously requested, via the **Federal Register**, on February 8, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public.

An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before January 26, 2022.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA HQ–OAR–2020–0624, online using *www.regulations.gov* (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection 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.

FOR FURTHER INFORMATION CONTACT: Muntasir Ali, Sector Policies and Program Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0833; email address: *ali.muntasir@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *https://www.regulations.gov,* or in person at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills apply to new and existing chemical recovery combustion sources at kraft, soda, sulfite, and stand-alone semichemical pulp mills, for which the chemical recovery combustion sources emit greater than or equal to 10 tons per year (tpy) of any one hazardous air pollutant (HAP) or greater than or equal to 25 tpy of any combination of HAPs. In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of any failures to meet applicable standards, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to 40 CFR part 63, subpart MM.

Form Numbers: 5900–520.

Respondents/affected entities: Chemical recovery combustion sources at kraft, soda, sulfite, and stand-alone semichemical pulp mills.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart MM).

Estimated number of respondents: 104 (total).

Frequency of response: Initially, occasionally, and semiannually.

Total estimated burden: 117,000 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $14,700,000 (per year), which includes $788,000 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an adjustment decrease in the total estimated burden as currently identified in the OMB Inventory of Approved Burdens. This decrease is not due to any program changes. This ICR includes a more accurate estimate of the number of existing facilities based on review of EPA's Enforcement and Compliance History Online (ECHO) and Greenhouse Gas Reporting Program (GHGRP) databases and consultations with the Agency's internal industry experts, and revises the previous number of 107 respondents down to 104. All 3 of the facilities removed are classified as Kraft Mills. The number of existing sources is adjusted downward to 254 and the number of ESPs is revised down to 178. This ICR also adjusts the growth rate from the previous ICR to remove the burden for a new source that was constructed in 2021, and removes burden from one-time initial compliance activities following the 2017 final rule (adjusting existing data acquisition systems to reflect the changes from the final rule). Therefore, the change in burden from the most-recently approved ICR, as currently identified in the OMB Inventory of Approved Burdens, is attributed to the alteration in total respondents, and because these standards have been in effect for more than three years. This ICR, by in large, reflects the on-going burden and costs for existing facilities. The decrease in the capital/startup cost is solely attributed to the decrease in total respondents. Since there are no significant changes in the regulatory requirements, the operation and maintenance (O&M) costs remain unaffected.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2021–28046 Filed 12–23–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2021–0942; FRL–9373–01–OGC]

Proposed Consent Decree, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with the Clean Air Act, as amended (CAA or the Act), notice is given of a proposed consent decree in *Center for Biological Diversity, et al.* v. *Regan,* No. 4:21–cv–06166–JST. On August 11, 2021, Plaintiffs Center for Biological Diversity, Center for Environmental Health, and Sierra Club (collectively ''Plaintiffs'') filed a complaint in the United States District Court for the Northern District of California. Plaintiffs alleged that the Environmental Protection Agency (EPA or the Agency) failed to perform certain non-discretionary duties in accordance with the Act to promulgate final actions for two nonattainment areas under the 2010 1-hour primary sulfur dioxide (SO_2) national ambient air quality standard (NAAQS): A final federal implementation plan (FIP) for the Detroit, Michigan SO_2 nonattainment area, and approval or disapproval of the state implementation plan (SIP) for the Baltimore and Anne Arundel Counties, Maryland SO_2 nonattainment area. The proposed consent decree would establish deadlines for EPA to take these actions.

DATES: Written comments on the proposed consent decree must be received by *January 26, 2022.*

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2021–0942, online at *https://www.regulations.gov* (EPA's preferred

method). Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID number for this action. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Additional Information about Commenting on the Proposed Consent Decree'' heading under the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov,* as there may be a delay in processing mail and faxes. Hand-deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

EPA continues to carefully and continuously monitor information from the Centers for Disease Control and Prevention (CDC), local area health departments, and our federal partners so that we can respond rapidly as conditions change regarding COVID–19.

FOR FURTHER INFORMATION CONTACT: Michael Thrift, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone (202) 564–8852; email address *thrift.mike@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining a Copy of the Proposed Consent Decree

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2021–0942) contains a copy of the proposed consent decree.

The electronic version of the public docket for this action contains a copy of the proposed consent decree, and is available through *https://www.regulations.gov.* You may use *https://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search.''

II. Additional Information About the Proposed Consent Decree

The proposed consent decree would establish deadlines for EPA to take final actions pursuant to Clean Air Act (CAA) sections 110(c)(1) and 110(k)(2) for two nonattainment areas under the 2010 1-hour primary sulfur dioxide (SO_2) national ambient air quality standard (NAAQS). Specifically, the consent decree would require: By September 30, 2022, that EPA promulgate a final federal implementation plan (FIP) for the Detroit, Michigan SO_2 nonattainment area under CAA section 110(c)(1), 42 U.S.C. 7410(c)(1); and by October 31, 2022, that EPA take final action to approve or disapprove the complete submitted state implementation plan (SIP) for the Baltimore and Anne Arundel Counties, Maryland, SO_2 nonattainment area under CAA section 110(k)(2), 42 U.S.C. 7410(k)(2).

In accordance with section 113(g) of the CAA, for a period of thirty (30) days following the date of publication of this document, the Agency will accept written comments relating to the proposed consent decree. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act.

III. Additional Information About Commenting on the Proposed Consent Decree

Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2021–0942, via *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from this docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* For additional information about submitting information identified as CBI, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document. Note that written comments containing CBI and submitted by mail may be delayed and deliveries or couriers will be received by scheduled appointment only.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *https://www.regulations.gov* website to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment.

Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

Gautam Srinivasan,

Associate General Counsel.

[FR Doc. 2021–27930 Filed 12–23–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2021–0660; FRL–9156–01–OCSPP–01]

Agency Information Collection Activities; Proposed Renewal and Consolidation of Two Currently Approved Collections Under Section 5 of the Toxics Substances Control Act; Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit a request to renew and consolidate two existing approved Information Collection Requests (ICRs) to the Office of Management and Budget (OMB). Before submitting the consolidated ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The consolidated ICR is entitled: ''TSCA Section 5 Reporting and Recordkeeping for Premanufacture Review of New Chemical Substances and Significant New Use Rules for New and Existing Chemical Substances'' and identified by EPA ICR No. 2702.01 and OMB Control No. 2070–NEW. EPA is consolidating these two existing approved ICRs because the information required to be collected and maintained is similar for both collection activities. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before February 25, 2022.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2021–0660, using the *Federal eRulemaking Portal at http://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 or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) is open to the public by appointment only. For the latest status information on EPA/DC and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Katherine Sleasman, Mission Support Division, (7101M), Office of Program Support, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–1204; email address: *sleasman.katherine@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A), 44 U.S.C. 3506(c)(2)(A), EPA specifically solicits comments and information to enable it to:

1. 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.

2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

3. Enhance the quality, utility, and clarity of the information to be collected.

4. 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. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What should I consider when I prepare my comments for EPA?

You may find the following suggestions helpful for preparing your comments:

- Explain your views as clearly as possible, include specific examples and describe any assumptions that you used.
- Provide copies of any technical information and/or data you used that support your views.
- If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
- Submit your comments by the deadline identified under **DATES**, and be sure to identify the docket ID number assigned to the ICR in the subject line on the first page of your response. You may also provide the ICR title and related EPA and OMB numbers.

III. What do I need to know about PRA?

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information subject to PRA approval unless it displays a currently valid OMB control number. The OMB control numbers for the EPA regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the preamble of the final rule, are further displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instruments or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in a list at 40 CFR 9.1.

As used in the PRA context, burden is defined in 5 CFR 1320.3(b).

IV. What information collection activity or ICR does this action apply to?

Title: TSCA Section 5 Reporting and Recordkeeping for Premanufacture Review of New Chemical Substances and Significant New Use Rules for New and Existing Chemical Substances.

ICR number: EPA ICR No. 2702.01.

OMB control number: OMB Control No. 2070–NEW.

ICR status: This is a new ICR that reflects the consolidation of the following two currently approved ICRs:

1. ''TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals'' (identified by EPA ICR No. 1188.12 and OMB Control No. 2070–0038), which is currently approved through July 31, 2022; and

2. ''Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances'' (identified by EPA ICR No.0574.18 and OMB Control No. 2070–0012), which is currently approved through December 31, 2022.

Abstract: The information collection activities in the consolidated ICR addresses the reporting and recordkeeping requirements associated with the new chemical substances review and regulatory program and the existing chemicals program administered by EPA under section 5 of the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the ''Lautenberg Act'') (15 U.S.C. 2604).

TSCA section 5 requires that any person who proposes to manufacture (which includes import) a ''new chemical'' (*i.e.,* a chemical not listed on the TSCA section 8(b) Inventory) must provide a premanufacture notice (PMN) or an exemption application to EPA at

least 90 days prior to commencing manufacture of that chemical and that EPA review such notice and take action as appropriate. EPA considers certain genetically engineered microorganisms to be chemical substances for purposes of the notification requirements found in TSCA section 5; the 90-day notice for microorganisms is a Microbial Commercial Activity Notice (MCAN).

Under TSCA section 5, EPA is authorized to determine that a non-ongoing use of a new or existing chemical substance is a significant new use and promulgate a significant new use rule (SNUR). When someone opts to pursue the manufacture (import) or processing of the chemical substance for that use, they must first submit a significant new use notice (SNUN) to EPA

from any person who proposes to manufacture or process a chemical for a use that is determined by EPA to be a ''significant new use.'' Note that the scope of this ICR only includes reporting of estimates for respondent activities associated with SNURs in instances where a SNUN is submitted. For more information on new and existing chemical SNURs, see a recent EPA Economic Analysis for new chemical SNURs issued under 40 CFR 721 Subpart D—Expedited Process, and the Supporting Statement for ''TSCA section 5(a)(2) Significant New Use Rules for Existing Chemicals Information Collection Request.''

TSCA section 5 requires EPA to make determinations before the conclusion of its review of the submitted notices regarding whether the manufacture, processing, distribution in commerce, use and/or disposal of the new chemical substances or the significant new use of the existing chemical substances may present unreasonable risk to health or the environment. EPA's determination on a chemical substance or new use will dictate how and to what extent the chemical's manufacture, use, processing and/or disposal may be restricted. If EPA fails to make a timely determination, fees may be refunded; however, nothing relieves EPA of its obligation to make a determination. EPA requires that the submitter of a PMN or MCAN inform EPA when non-exempt commercial manufacture of the substance in question actually begins by submitting a Notice of Commencement; EPA would then add the new chemical substance to the TSCA section 8(b) Inventory.

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b), and regulations that interpret TSCA section 12(b) appear at 40 CFR part 707 and the associated paperwork activities and burdens are approved under OMB Control No. 2070–0030, ICR entitled ''Notification of Chemical Exports—TSCA Section 12(b),'' identified by EPA ICR No. 0795.16.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to be between 17 to 526 hours per response. The consolidated ICR, a copy of which is available in the docket, provides a detailed explanation of this estimate, which is only briefly summarized here:

Respondents/Affected entities: Entities potentially affected by this ICR are chemical manufacturers (defined by statute to include importers) and processors, *e.g.,* entities identified by the North American Industrial Classification System (NAICS) codes 325, Chemicals and Allied Products Manufacturers, and 324, Petroleum Refining.

Estimated total number of potential respondents: 234.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 5.74.

Estimated total annual burden hours: 136,292 hours.

Estimated total annual costs: $ 37,354,814. This includes an estimated burden cost of $ 37,354,814 and an estimated cost of $ 0 for non-burden hour paperwork costs, *e.g.,* capital investment or maintenance and operational costs.

V. Are there changes in the estimates from the last approvals?

The consolidation of the currently approved ICRs is expected to result in an overall decrease of 55,863 burden hours and $ 17,188,154 burden costs when compared to the total combined burden and costs that is currently approved by OMB. This decrease in the total estimated burden and costs is primarily due to the declining number of TSCA section 5 submissions for new chemicals, and other adjustments made in EPA's estimates of the number of respondents, as well as the related burden and costs estimates. This change is an adjustment.

In addition, OMB has requested that EPA move towards using the 18-question format for ICR Supporting Statements used by other federal agencies and departments and that is based on the submission instructions established by OMB in 1995, replacing the alternate format developed by EPA and OMB prior to 1995. The Agency does not expect this change in format to result in substantive changes to the information collection activities or related estimated burden and costs.

VI. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the consolidated ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity for the public to submit additional comments for OMB consideration. If you have any questions about this ICR or the approval process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: December 21, 2021.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2021–28066 Filed 12–23–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2020–0638; FRL–9385–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; National Emission Standards for Hazardous Air Pollutants (NESHAP) for Leather Finishing Operations) (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), National Emission Standards for Hazardous Air Pollutants (NESHAP) for Leather Finishing Operations (EPA ICR Number 1985.10, OMB Control Number 2060–0478), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through February 28, 2022. Public comments were previously requested, via the **Federal Register**, on February 8, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before January 26, 2022.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2020–0638, online using *www.regulations.gov* (our preferred method) or by mail to EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection 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.

FOR FURTHER INFORMATION CONTACT: Muntasir Ali, Sector Policies and Program Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0833; email address: *ali.muntasir@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *https://www.regulations.gov,* or in person at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *https://www.epa.gov/dockets.*

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Leather Finishing Operations (40 CFR part 63, subpart TTTT) apply to existing and new leather finishing facilities that are major sources of HAP or are collocated with other sources that are individually or collectively a major source of HAP emissions. Owners and operators of affected facilities are required to submit initial notifications, performance tests, and periodic reports. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are used by the EPA to determine compliance with these standards.

Form Numbers: None.

Respondents/affected entities: Leather finishing operations.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart TTTT).

Estimated number of respondents: 4 (total).

Frequency of response: Initially, occasionally and annually.

Total estimated burden: 138 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $16,300 (per year), which includes $0 in annualized capital/startup expense and/or operation & maintenance costs.

Changes in the Estimates: There is an adjustment increase in the total estimated burden as currently identified in the OMB Inventory of Approved Burdens. This increase is not due to any program changes. The change in the burden and cost estimates occurred because the previous ICR assumed that respondents would only need to familiarize with the regulatory requirements once, during the year in which rule revisions occurred, and omitted familiarization with the regulatory requirements in the years following. This ICR assumes that respondents will need to familiarize with the regulatory requirements every year. The overall result is a small increase in burden hours and costs. Aside from this minor change in burden hours, the only other change is due to a slight increase in costs, which is wholly due to the use of updated labor rates. This ICR uses labor rates from the most-recent Bureau of Labor Statistics report (September 2020) to calculate respondent burden costs.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2021–28047 Filed 12–23–21; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

[Notice–MA–2021–08; Docket No. 2021–0002; Sequence No. 33]

Relocation Allowances—Extended Waiver of Certain Federal Travel Regulation (FTR) Provisions During the COVID–19 Pandemic

AGENCY: Office of Government-wide Policy (OGP), General Services Administration (GSA).

ACTION: Notice of GSA Bulletin FTR 22–04, extended waiver of certain federal travel regulation (FTR) provisions during the Coronavirus disease 2019 (COVID–19) pandemic.

SUMMARY: This GSA Bulletin FTR 22–04 informs agencies that certain provisions of the FTR governing official relocation travel and renewal agreement travel (RAT) may continue to be temporarily waived for the period of time stated in the bulletin. This bulletin also rescinds an expiring GSA bulletin pertaining to relocation allowances during the pandemic and re-establishes information therein via this new bulletin.

DATES: *Applicability Date:* This notice is retroactively effective for official relocation travel performed after March 13, 2019, one year prior to the date of the Presidential national emergency proclamation concerning COVID–19.

FOR FURTHER INFORMATION CONTACT: Mr. Rick Miller, Senior Policy Analyst, Office of Government-wide Policy, Office of Asset and Transportation Management, at 202–501–3822, or *travelpolicy@gsa.gov.* Please cite Notice of GSA Bulletin FTR 22–04.

SUPPLEMENTARY INFORMATION:

Background: Federal agencies authorize relocation entitlements to those individuals listed at FTR § 302–1.1 and those assigned under the Government Employees Training Act (GETA) (5 U.S.C. chapter 41). Since the Presidential national emergency proclamation issued March 13, 2020 concerning COVID–19, the pandemic has resulted in various travel-related disruptions to relocating employees. Accordingly, GSA issued Bulletin FTR 21–04 (86 FR 14326 March 15, 2021)(which rescinded and replaced related GSA Bulletins FTR 20–06 (85 FR 23029 April 24, 2020) and FTR 21–02 (85 FR 59311 September 21, 2020)), to allow agencies to determine whether to implement waivers of time limits established by the FTR for completion of all aspects of relocation, temporary storage of household goods (HHG) shipments, house hunting trips (HHT),

and time remaining in a second tour of duty upon return from renewal agreement travel (RAT). GSA Bulletin FTR 21–04 and the waiver provisions therein is set to expire on December 31, 2021.

As COVID–19 has continued to produce uncertainty and create difficulties for relocating individuals, GSA is extending certain FTR waivers by rescinding GSA Bulletin FTR 21–04 and re-establishing the information therein by issuance of this new GSA Bulletin FTR 22–04 with a later expiration date. GSA Bulletins FTR 20–06 and FTR 21–02 remain rescinded. The new GSA Bulletin FTR 22–04 can be viewed at *https://www.gsa.gov/ftrbulletins.*

Dated: December 21, 2021.

Krystal J. Brumfield,

Associate Administrator, Office of Government-wide Policy.

[FR Doc. 2021–28044 Filed 12–23–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-22–22AW; Docket No. CDC–2021–0126]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled *NCEH DLS Laboratory Quality Assurance Programs.* CDC's National Center for Environmental Health (NCEH) Division of Laboratory Science (DLS) provides quality assurance in the form of quality control samples and technical assistance to laboratories to improve analytical accuracy and reliability of tests. Participating laboratories return results to CDC to assess performance.

DATES: CDC must receive written comments on or before February 25, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0126 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *regulations.gov.*

Please note: Submit all comments through the federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;

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. Enhance the quality, utility, and clarity of the information to be collected;

4. 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; and

5. Assess information collection costs.

Proposed Project

NCEH DLS Quality Assurance Programs—Existing Collection in Use Without an OMB Control Number—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Laboratory Quality Assurance (QA) encompasses a range of activities that enable laboratories to achieve and maintain high levels of accuracy and proficiency despite changes in test methods, instrumentation, analytes, source materials, and the volume of specimens tested.

The CDC Division of Laboratory Sciences (DLS) QA programs operate out of multiple laboratories within the division. They establish the baseline measurements and provide calibration and/or quality control (QC) samples that laboratories around the world rely on to develop and improve methods with acceptable levels of accuracy and reliability and, in some cases, meet certain required certifications or accreditation. Laboratories use DLS-developed samples to test the quality and accuracy of their methods/assays. Participating laboratories enroll in the DLS QA program that fits their needs (*i.e.,* external quality assurance/performance assessment, proficiency testing, accuracy-based monitoring, or standardization/harmonization). After the laboratories receive DLS QA samples and perform their measurements, they return test results to DLS. DLS then evaluates the data using statistical methods and reports back to the laboratories on their analytical performance. Laboratories may receive additional technical assistance (TA)/troubleshooting to improve their method performance as needed. DLS programs are offered at different frequencies.

There are 13 DLS QA programs conducted by the following five DLS branches. These programs provide materials and test result analysis to laboratories for the purpose of

improving and/or standardizing test performance.

- Clinical Chemistry Branch (CCB)
  - Accuracy-based Laboratory Monitoring Programs (AMP)
  - Lipid Standardization Program (LSP) for Clinical Biomarkers
  - Cholesterol Reference Method Laboratory Network (CRMLN)
  - Hormone Standardization (HoST) Program
  - Vitamin D Standardization Certification Program (VDSCP)
- Nutrition Biomarkers Branch (NBB)
  - Vitamin A Laboratory—External Quality Assurance (VITAL–EQA)
  - Quality Assurance Method Performance Verification (MPV) for Folate Microbiologic Assay (MBA)
  - Quality Assurance Method Performance Verification (MPV) for Micronutrients
- Organic Analytical Toxicology Branch (OATB)
  - Biomonitoring Quality Assurance Support Program (BQASP)
- Inorganic Radiation and Analytical Toxicology Branch (IRATB)
  - Proficiency in Arsenic Speciation (PAsS) Program
  - Ensuring the Quality of Urinary Iodine Procedures (EQUIP)
  - Lead and Multielement Proficiency (LAMP) Testing Program
- Newborn Screening and Molecular Biology Branch (NSMBB)
  - Newborn Screening and Quality Assurance Program (NSQAP)

All 13 CDC QA programs help improve the accuracy and reliability of tests performed by laboratories in patient care, research, commercial and public health settings. They also help to make measurement results among research studies and among clinical laboratories more comparable. Collectively, these programs improve the quality of laboratory tests that measure environmental exposures and chronic disease biomarkers (including nutritional indicators and hormones) to better inform critical patient care and public health decisions for an expansive host of health outcomes such as rare heritable disorders in newborns, endocrine disorders, maternal health and risk of birth defects, bone, kidney and cardiovascular disease, cancers (including breast cancer), diabetes, and thyroid and hormone dysregulation.

The estimated annualized burden hours were determined as follows. There are 1,720 participating laboratories across the 13 DLS QA programs. A ''respondent'' refers to a single laboratory represented by an individual laboratory analyst who would record the data from their testing results in the supplied data submission form(s). Depending on the program, the average burden per response for the enrollment and data submission forms was determined to be five minutes up to two hours through firsthand experience in testing usability/data entry of forms. The number of respondents fluctuates minimally each year and an average number of participants per program was estimated by each program based on previous years' participation and trends in participation rate since the inception of each program. CDC has estimated the annualized burden for these 13 programs to be 4,293 hours per year.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
CCB Accuracy-based Laboratory Monitoring Programs (AMP)					
Academic/University Research Lab.	AMP Enrollment and Data Submission Form	10	1	25/60	4
	AMP Enrollment and Data Submission Form	10	4	45/60	30
Private Research Lab	AMP Enrollment and Data Submission Form	3	1	25/60	1
	AMP Enrollment and Data Submission Form	3	4	45/60	9
Routine Clinical Lab	AMP Enrollment and Data Submission Form	20	1	25/60	8
	AMP Enrollment and Data Submission Form	20	4	45/60	60
CCB Lipid Standardization Program (LSP)					
Academic/University Research Lab.	LSP Enrollment and Data Submission Form	20	1	25/60	8
	LSP Enrollment and Data Submission Form	20	4	45/60	60
Private Research Lab	LSP Enrollment and Data Submission Form	7	1	25/60	3
	LSP Enrollment and Data Submission Form	7	4	45/60	21
Routine Clinical Lab	LSP Enrollment and Data Submission Form	40	1	25/60	17
	LSP Enrollment and Data Submission Form	40	4	45/60	120
CCB Cholesterol Reference Method Laboratory Network (CRMLN)					
CRMLN Network Laboratories	CRMLN Enrollment Email	15	1	10/60	3
	CRMLN Data Submission Form	15	2	2	60
CCB Hormone Standardization (HoST) Program					
Assay Manufacturers	HoSt Enrollment and Data Submission Form	60	1	30/60	30
	HoSt Enrollment and Data Submission Form	60	4	1	240
Lab Developed Tests (LDT) Manufacturers.	HoSt Enrollment and Data Submission Form	40	1	30/60	20
	HoSt Enrollment and Data Submission Form	40	4	1	160
End-user/Labs	HoSt Enrollment and Data Submission Form	20	1	30/60	10
	HoSt Enrollment and Data Submission Form	20	4	1	80

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
CCB Vitamin D Standardization Certification Program (VDSCP)					
Assay Manufacturers	VDSCP Enrollment and Data Submission Form.	60	1	30/60	30
	VDSCP Enrollment and Data Submission Form.	60	4	1	240
LDT Manufacturers	VDSCP Enrollment and Data Submission Form.	40	1	30/60	20
	VDSCP Enrollment and Data Submission Form.	40	4	1	160
End-user/Labs	VDSCP Enrollment and Data Submission Form.	20	1	30/60	10
	VDSCP Enrollment and Data Submission Form.	20	4	1	80
NBB Vitamin A Laboratory—External Quality Assurance (VITAL-EQA)					
Academic/University Research Lab.	VITAL-EQA Enrollment Form	30	1	25/60	13
	Data Submission Form	30	2	45/60	45
Government/Ministry of Health Lab.	VITAL-EQA Enrollment Form International	30	1	25/60	13
	Data Submission Form	30	2	45/60	45
Private Research Lab	VITAL-EQA Enrollment Form	15	1	25/60	6
	Data Submission Form	15	2	45/60	23
Clinical Lab	VITAL-EQA Enrollment Form	15	1	25/60	6
	Data Submission Form	15	2	45/60	23
NBB Quality Assurance Method Performance Verification (MPV) for Folate Microbiologic Assay (MBA)					
Academic/University Research Lab.	MPV Folate MBA Enrollment and Data Submission Form.	15	1	25/60	6
	MPV Folate MBA Enrollment and Data Submission Form.	15	4	45/60	45
Government/Ministry of Health Lab.	MPV Folate MBA Enrollment and Data Submission Form.	15	1	25/60	6
	MPV Folate MBA Enrollment and Data Submission Form.	15	4	45/60	45
Private Research Lab	MPV Folate MBA Enrollment and Data Submission Form.	5	1	25/60	2
	MPV Folate MBA Enrollment and Data Submission Form.	5	4	45/60	15
Clinical Public Health Lab	MPV Folate MBA Enrollment and Data Submission Form.	5	1	25/60	2
	MPV Folate MBA Enrollment and Data Submission Form.	5	4	45/60	15
NBB Quality Assurance Method Performance Verification (MPV) for Micronutrients					
Academic/University Research Lab.	MPV Micronutrients Enrollment and Data Submission Form.	20	1	25/60	8
	MPV Micronutrients Enrollment and Data Submission Form.	20	4	45/60	60
Government/Ministry of Health Lab.	MPV Micronutrients Enrollment and Data Submission Form.	20	1	25/60	8
	MPV Micronutrients Enrollment and Data Submission Form.	20	4	45/60	60
Private Research Lab	MPV Micronutrients Enrollment and Data Submission Form.	10	1	25/60	4
	MPV Micronutrients Enrollment and Data Submission Form.	10	4	45/60	30
Clinical Public Health Lab	MPV Micronutrients Enrollment and Data Submission Form.	10	1	25/60	4
	MPV Micronutrients Enrollment and Data Submission Form.	10	4	45/60	30
OATB Biomonitoring Quality Assurance Support Program (BQASP)					
State Public Health Labs	BQASP Enrollment Email	10	1	5/60	1

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
	BQASP Data Submission Form	10	1	45/60	8
IRATB Proficiency in Arsenic Speciation (PAsS) Program					
Public Health Labs	PAsS Enrollment Form	28	1	10/60	5
	PAsS Data Submission Form	28	4	10/60	19
IRATB Ensuring the Quality of Urinary Iodine Procedures (EQUIP)					
Public Health Labs	EQUIP Enrollment Form	240	1	10/60	41
	EQUIP Data Submission Form	240	3	10/60	122
IRATB Lead and Multielement Proficiency (LAMP) Testing Program					
Public Health Labs	LAMP Enrollment Form	226	1	10/60	39
	LAMP Data Submission Form	226	4	10/60	154
NSMBB Newborn Screening and Quality Assurance Program (NSQAP)					
Domestic NBS Labs	NSQAP Enrollment Form	71	1	10/60	12
	NSQAP Data Submission Portal Quality Control (QC).	71	2	45/60	107
	NSQAP Data Submission Portal Biochemical & Molecular Proficiency Tests (PT).	71	3	45/60	160
International NBS Labs	NSQAP Enrollment Form	568	1	10/60	95
	NSQAP Data Submission Portal QC	568	2	45/60	129
	NSQAP Data Submission Portal Biochemical & Molecular PT.	568	3	45/60	1,278
NBS Test Manufacturers	NSQAP Enrollment Form	32	1	10/60	5
	NSQAP Data Submission Portal QC	32	2	45/60	48
	NSQAP Data Submission Portal Biochemical & Molecular PT.	32	3	45/60	72
Total		1,720			4,293

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–28033 Filed 12–23–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–1235]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Assessments to Inform Program Refinement for HIV, other STD, and Pregnancy Prevention among Middle and High-School Aged Youth'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on August 2, 2021, to obtain comments from the public and affected agencies. CDC received two comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Assessments to Inform Program Refinement for HIV, other STD, and Pregnancy Prevention among Middle and High-School Aged Youth (OMB Control No. 0920–1235, Exp. 05/31/2022)—Extension—National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) requests three-year OMB approval for the extension of a Generic Information Collection Request (ICR) package (OMB Control No. 0920–1235, Exp. 05/31/2022) that supports collection of quantitative and qualitative information from adolescents (ages 11–19) and their parents/caregivers for the purpose of needs assessment and program refinement for programs and services to prevent HIV, other sexually transmitted diseases (STDs), and pregnancy among middle and high school aged adolescents.

NCHHSTP conducts behavioral and health service assessments and research projects as part of its response to the domestic HIV/AIDS epidemic, STD prevention, TB elimination and viral hepatitis control with national, state, and local partners. Adolescents are a population with specific developmental, health and social, and resource needs, and their health risk factors and access to health care are addressed as a primary mission by the Division of Adolescent and School Health (DASH). Adolescents are also a population of interest for several other NCHHSTP divisions. The assessment and research conducted by NCHHSTP is one pillar upon which recommendations and guidelines are revised and updated, and these recommendations and guidelines require a foundation of scientific evidence.

Assessment of programmatic practices for adolescents helps to assure effective and evidence-based sexual risk reduction practices and efficient use of resources. Such assessments also help to improve programs through better identification of strategies relevant to adolescents as a population, as well as specific sub-groups of adolescents at highest risk for HIV and other STDs so that programs can be better tailored for them.

The information collection requests under this generic package are intended to allow for data collection with two types of respondents:

- Adolescents (11–19 years old) of middle and high school age; and
- Parents and/or caregivers of adolescents of middle and high school age. For the purposes of this generic package, parents/caregivers include the adult primary caregiver(s) for a child's basic needs (*e.g.,* food, shelter, and safety). This includes biological parents; other biological relatives such as grandparents, aunts, uncles, or siblings; and non-biological parents such as adoptive, foster, or stepparents.

The types of information collection activities included in this generic package are:

(1) Quantitative data collection through electronic, telephone, or paper questionnaires to gather information about programmatic and service activities related to the prevention of HIV and other STDs among adolescents of middle- and high-school age.

(2) Qualitative data collection through electronic, telephone, or paper means to gather information about programmatic and service activities related to the prevention of HIV and other STDs among adolescents of middle- and high-school age. Qualitative data collection may involve focus groups and in-depth interviewing through group interviews, and cognitive interviewing.

For adolescents, data collection instruments will include questions on demographic characteristics; experiences with programs and services to reduce the risk of HIV and other STD transmission; and knowledge, attitudes, behaviors, and skills related to sexual risk and protective factors on the individual, interpersonal, and community levels. For parents and caregivers, data collection instruments will include questions on demographic characteristics as well as parents'/caregivers' (1) perceptions about programs and services provided to adolescents; (2) knowledge, attitudes, and perceptions about their adolescents' health risk and protective behaviors; and (3) parenting knowledge, attitudes, behaviors, and skills.

Any data collection request put forward under this generic clearance will identify the programs and/or services to be informed or refined, and will include a crosswalk of data elements to the aspects of the program the project team seeks to inform or refine. Because this request includes a wide range of possible data collection instruments, specific requests will include items of information to be collected and copies of data collection instruments. It is expected that all data collection instruments will be pilot tested, and will be culturally, developmentally, and age appropriate for the adolescent populations included.

Similarly, parent data collection instruments will be pilot-tested, and the data collection instruments will reflect the culture, developmental stage, and age of the parents' adolescent children. All data collection procedures will receive review and approval by an Institutional Review Board (IRB) for the Protection of Human Subjects and follow appropriate consent and assent procedures as outlined in the IRB approved protocols. These will be described in the individual information collection requests put forward under this Generic package.

The table below provides the estimated annualized response burden for up to 15 individual data collections per year under this generic clearance. CDC requests approval for an estimated 57,584 annual burden hours. Participation of respondents is voluntary. There is no cost to participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Middle and High School Age Adolescents	Youth Questionnaire	20,000	1	50/60
Middle and High School Age Adolescents	Pre/Post youth questionnaire	10,000	2	50/60
Middle and High School Age Adolescents	Youth interview/focus group guide	3,000	2	90/60
Parents/caregivers of adolescents	Parent/Caregiver questionnaire	7,500	2	25/60
Parents/caregivers of adolescents	Parent/Caregiver interview/focus group guide	3,000	2	90/60

Jeffrey M. Zirger,
Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–28040 Filed 12–23–21; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2021–0001]

Final Revised Vaccine Information Materials

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: Under the National Childhood Vaccine Injury Act (NCVIA), the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) develops vaccine information materials that all healthcare providers are required to give to any patient (or to the patient's parent or legal representative in the case where the patient is a minor child) prior to administration of specific vaccines. On January 11, 2021, CDC published a notice in the **Federal Register** (86 FR 1977) seeking public comments on proposed updated vaccine information materials for vaccines covered by the National Vaccine Injury Compensation Program. Following review of comments submitted and consultation as required under the law, CDC has finalized the materials. By March 31, 2022, all healthcare providers must discontinue use of the previous editions and provide copies of these updated vaccine information materials prior to immunization.

DATES: No later than March 31, 2022, each healthcare provider who administers a vaccine covered by the National Vaccine Injury Compensation Program to any child or adult in the United States shall discontinue use of previous editions and provide copies of the updated vaccine information materials referenced in this notice, in conformance with the CDC Instructions for Use of Vaccine Information Statements dated October 15, 2021, prior to administering such vaccinations.

FOR FURTHER INFORMATION CONTACT: Suzanne Johnson-DeLeon, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop: H 24–6, 1600 Clifton Road NE, Atlanta, Georgia 30329. Telephone: (404) 639–8817.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986 (Pub. L. 99–660), as amended by section 708 of Public Law 103–183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa–26, requires the Secretary of Health and Human Services (the Secretary) to develop and disseminate vaccine information materials for distribution by all healthcare providers in the United States to any patient (or to the patient's parent or legal representative in the case where the patient is a minor child) receiving vaccines covered under the National Vaccine Injury Compensation Program.

Development and revision of the vaccine information materials, also known as Vaccine Information Statements, have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires the materials be developed, or revised, after notice to the public, with a 60-day comment period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate healthcare provider and parent organizations, and the Food and Drug Administration. Section 2126 also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

(1) A concise description of the benefits of the vaccine;

(2) A concise description of the risks associated with the vaccine;

(3) A statement of the availability of the National Vaccine Injury Compensation Program; and

(4) Such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella, and poliomyelitis vaccines. Since April 15, 1992, any healthcare provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines. Since then, the following vaccines have been added to the National Vaccine Injury Compensation Program, requiring use of vaccine information materials for them as well: hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, rotavirus, hepatitis A, meningococcal, human papillomavirus (HPV), and seasonal influenza vaccines. Instructions for use of the vaccine information materials are found on the CDC website at: *https://www.cdc.gov/vaccines/hcp/vis/about/required-use-instructions.html.*

Revised Vaccine Information Materials

The revised vaccine information materials referenced in this notice were developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and parent and healthcare provider organizations. Following consultation and review of comments submitted, the vaccine information materials pertaining to vaccines covered under the National Vaccine Injury Compensation Program have been finalized and are available to download from *https://www.cdc.gov/vaccines/hcp/vis/index.html* or *http://www.regulations.gov* (see Docket Number CDC–2021–0001). The revised Vaccine Information Statements are the following:

''DTaP (Diphtheria, Tetanus, and Pertussis) Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Hepatitis A Vaccine: What You Need to Know,'' publication date October 15, 2021.

''Hepatitis B Vaccine: What You Need to Know,'' publication date October 15, 2021.

''*Haemophilus influenzae* type b (Hib) Vaccine: What You Need to Know,'' publication date August 6, 2021.

''HPV (Human Papillomavirus) Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Influenza (Flu) Vaccine (Live, Intranasal): What You Need to Know,'' publication date August 6, 2021.

''Influenza (Flu) Vaccine (Inactivated or Recombinant): What You Need to Know,'' publication date August 6, 2021.

''MMR Vaccine (Measles, Mumps, and Rubella): What You Need to Know,'' publication date August 6, 2021.

''MMRV Vaccine (Measles, Mumps, Rubella, and Varicella): What You Need to Know,'' publication date August 6, 2021.

''Meningococcal ACWY Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Meningococcal B Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Pneumococcal Conjugate Vaccine (PCV13): What You Need to Know,'' publication date August 6, 2021.

''Polio Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Rotavirus Vaccine: What You Need to Know,'' publication date October 15, 2021.

''Tdap (Tetanus, Diphtheria, and Pertussis) Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Td (Tetanus and Diphtheria) Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Varicella (Chickenpox) Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Your Child's First Vaccines: What You Need to Know,'' publication date October 15, 2021.

With publication of this notice, by March 31, 2022, all healthcare providers must discontinue use of the previous editions and provide copies of these updated vaccine information materials prior to immunization in conformance with CDC Instructions for Use of Vaccine Information Statements dated October 15, 2021.

Dated: December 20, 2021.

Angela K. Oliver,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2021–27929 Filed 12–23–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–0852]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Prevalence Survey of Healthcare-Associated Infections and Antimicrobial Use in U.S. Acute Care Hospitals to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on August 13, 2021 to obtain comments from the public and affected agencies. CDC received one non-substantive comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Prevalence Survey of Healthcare-Associated Infections and Antimicrobial Use in U.S. Acute Care Hospitals (OMB Control No. 0920–0852, Exp. 10/31/2022)—Extension—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Preventing healthcare-associated infections (HAIs) and improving antimicrobial use (AU) are CDC and national priorities. An essential step in reducing the occurrence of HAIs is to accurately estimate the burden of these infections in U.S. acute care hospitals and to describe the types of HAIs and causative pathogens. Periodic assessments of the magnitude and types of HAIs and AU occurring in all patient populations within acute care hospitals are needed to inform decisions by policy makers and hospital infection control personnel (ICP) regarding appropriate targets and strategies for HAI prevention and antimicrobial stewardship.

Since 2009, CDC has conducted four prevalence surveys (*i.e.,* pilot survey in 2009, limited-scale survey in 2010, and two full-scale surveys in 2011 and 2015) in partnership with the CDC's Emerging Infections Program (EIP) sites. Findings from the most recent survey showed a reduction in the percentage of patients with healthcare-associated infections compared with 2011. We granted approval from OMB to conduct the fifth survey in 2020, but due to the COVID–19 pandemic the survey was postponed to 2023.

Minor adjustments to data collection instruments since the previous 2019 OMB approval have been made. These adjustments were made to enhance future analyses and utility of the survey data. These changes are non-substantive and are not expected to increase the public reporting burden. An extension of the prevalence survey's existing OMB approval is sought to allow a repeat HAI and AU Prevalence Survey to be performed in 2023. A repeat survey will allow assessment of changes in HAI and AU prevalence, pathogen distribution, and quality of antimicrobial prescribing. These data will also allow CDC and its partners to continue to monitor HAI and AU trends, to measure progress in meeting national targets, and to further refine prevention strategies.

In the 2023 survey, data collection will occur within acute care general hospitals of varying size in each of the 10 EIP sites (*i.e.,* CA, CO, CT, GA, MD, MN, NM, NY, OR, & TN). Infection Control Personnel in participating hospitals may assist EIP site personnel in collecting demographic and limited clinical data from the electronic or paper-based medical records of a sample of randomly selected patients on a single day in 2023. Patients will not be interviewed, and no direct interaction with patients will occur. Hospital and patient-level data will be collected using unique identification codes. EIP site personnel will submit hospital and patient-level data to CDC using a secure data management system.

Based on experiences from previous surveys, the time required to complete the Healthcare Facility Assessment Form (HFA) and Patient Information Form (PIF) is estimated to be 45 and 17 minutes, respectively. To conduct the full-scale survey in a three-year approval period, 100 hospital respondents will complete the HFA once, and the PIF on average 63 times per year. The total estimated annualized public burden is 1,860 hours, which represents no change from the 2019 OMB approval.

To assess changes in HAIs and AU over time, EIP sites will seek participation from the same hospitals that participated in prior surveys. These hospitals were originally selected for participation using a stratified random

sampling scheme based on the number of staffed acute care beds (*i.e.,* small: <150 staffed beds; medium: 151–399 staffed beds; large: >400 staffed beds). Each site will also have the option to recruit additional hospitals for a total of up to 30 in each site. As in previous surveys, hospital participation will remain voluntary. Within each participating hospital, EIP site personnel will establish patient sample size targets based on the number of staffed acute care beds (*e.g.,* up to 75 patients in small hospitals, 75 patients in medium hospitals, and 100 patients in large hospitals).

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Hospital Staff (Infection Preventionist)	HFA	100	1	45/60
	PIF	100	63	17/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–28032 Filed 12–23–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–0017]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Application for Training'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on July 26, 2021 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice, and provided a standard response. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Application for Training (OMB Control No. 0920–0017, Exp. 4/30/2022)—Revision—Center for Surveillance, Epidemiology, and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The mission of CDC's Division of Scientific Education and Professional Development (DSEPD) is to support the development of a competent, sustainable, and empowered public health workforce. Professionals in public health, epidemiology, medicine, economics, information science, veterinary medicine, nursing, public policy, and other related professions seek professional development opportunities (both accredited and nonaccredited) through two CDC learning management systems. These two learning management systems are Training and Continuing Education Online (TCEO) (for accredited courses) and CDC TRAIN (for nonaccredited courses developed by CDC programs, grantees, and other funded partners). These two systems allow for the public health workforce to broaden their knowledge and skills to improve the science and practice of public health for domestic and international impact. Both systems currently involve related, but separate, information collection tools and information technology platforms.

The CDC seeks approval to implement changes as follows:

1. In TCEO, two additional accreditation types will be added as options a learner can select, to allow for master certified health education specialists and physician assistants to earn continuing education. Additional text is added to clarify what is requested for the CPE (Continuing Pharmacy Education) ID number.

2. CDC TRAIN is added as a data collection platform. The addition of CDC TRAIN to this request also supports the eventual merger of the two learning systems, a process that is underway and described further below. Adding CDC TRAIN to this revision also would allow CDC programs to collect standardized post-course evaluation data for program improvement, similar to what is done currently in TCEO (see #3).

3. The two standard training evaluation tools in CDC TRAIN are added to evaluate a training's effectiveness (learning transfer and quality training) as well as its promotion, delivery, and learner satisfaction at two time points

(immediate post-course and delayed follow-up). This information will provide helpful feedback for training improvement. The new tools for CDC TRAIN were developed based on an extensive feedback process from training developers and evaluators and cognitive testing to refine the questions. To prepare for the future merger of TCEO and CDC TRAIN systems, the content of these tools also include questions that are required for accreditation (from the TCEO Post-Course Evaluation and TCEO Follow-Up Evaluation tools).

Currently in both platforms, data will be collected online, using secure, electronic, web-based, password-protected portals. Respondents will include educational developers requesting accreditation for their trainings (TCEO) and public health and healthcare professionals who seek training (CDC TRAIN and TCEO). No statistical methods will be used to analyze the information collected. CDC will use identifiable information in TCEO to track participant completion of educational activities to facilitate required reporting to earn continuing education credits, hours, or units. Aggregate and non-aggregate data from the evaluations in TCEO and CDC TRAIN will be used to improve educational activities and assess learning outcomes.

Overall, this revision request seeks to achieve three objectives. First, it will allow for short-term continuation of the TCEO system and its ability to serve individuals seeking accredited training. The demand for TCEO's trainings and accreditation remains high and ongoing. Second, it will allow for more standardized evaluation of trainings offered through CDC TRAIN, based on the data collection methods and tools already used successfully in TCEO. Third, by proposing CDC TRAIN as an approved platform, it lays a key step for the eventual discontinuation of the TCEO platform and incorporation of TCEO's trainings and tools into the CDC TRAIN platform. Future change requests for this revision likely will involve additional steps in this merger process, such as the retirement of TCEO as a platform, the discontinuation of the TCEO-specific training evaluation tools in favor of CDC TRAIN's forms, and the absorption of TCEO's trainings and other features into the CDC TRAIN platform. These anticipated changes should not affect the burden hours or type of information that learners are asked to provide. These future changes should improve learners' experiences, through more standardization and centralization; and they should result in significant program management efficiencies for CDC and its training partners.

OMB approval is requested for three years. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden is 288,150 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Educational Developers (Health Educators) ..	TCEO Proposal	130	1	5
Public Health and Health Care Professionals (Learners).	TCEO New Participant Registration	300,000	1	5/60
Public Health and Health Care Professionals (Learners).	TCEO Post-Course Evaluation	300,000	3	10/60
Public Health and Health Care Professionals (Learners).	TCEO Follow-up Evaluation	30,000	3	3/60
Public Health and Health Care Professionals (Learners).	CDC TRAIN Immediate Post-Course Evaluation Tool.	300,000	3	7/60
Public Health and Health Care Professionals (Learners).	CDC TRAIN Delayed Follow-Up Evaluation Tool.	30,000	3	2/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–28030 Filed 12–23–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–0666]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled National Healthcare Safety Network (NHSN) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on September 27, 2021 to obtain comments from the public and affected agencies. CDC received four non-substantive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570.

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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Healthcare Safety Network (NHSN) (OMB Control No. 0920–0666, Exp. 12/31/2023)—Revision—National Center for Emerging and Zoonotic Infection Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Healthcare Quality Promotion (DHQP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC) collects data from healthcare facilities in the National Healthcare Safety Network (NHSN) under OMB Control No. 0920–0666. NHSN provides facilities, states, regions, and the nation with data necessary to identify problem areas, measure the progress of prevention efforts, and ultimately eliminate healthcare-associated infections (HAIs), nationwide. Additionally, NHSN allows healthcare facilities to track blood safety errors and various healthcare-associated infection prevention practice methods, such as healthcare personnel influenza vaccine status and corresponding infection control adherence rates. NHSN currently has seven components: Patient Safety (PS), Healthcare Personnel Safety (HPS), Biovigilance (BV), Long-Term Care Facility (LTCF), Outpatient Procedure (OPC), Dialysis Component, and the Neonatal Component. NHSN has increasingly served as the operating system for HAI reporting compliance through legislation established by the states. As of April 2020, 36 states, the District of Columbia and the City of Philadelphia, Pennsylvania have opted to use NHSN as their primary system for mandated reporting. Reporting compliance is completed by healthcare facilities in their respective jurisdictions, with emphasis on those states and municipalities acquiring varying consequences for failure to use NHSN. Additionally, healthcare facilities in five U.S. territories (Puerto Rico, American Samoa, the U.S. Virgin Islands, Guam, and the Northern Mariana Islands) are voluntarily reporting to NHSN. Additional territories are projected to follow with similar use of NHSN for reporting purposes.

NHSN's data is used to aid in the tracking of HAIs and guide infection prevention activities/practices that protect patients. The Centers for Medicare and Medicaid Services (CMS), and other payers use these data to determine incentives for performance at healthcare facilities across the US and surrounding territories. Members of the public may also use some protected data to inform their selection among available providers.

Each of these parties is dependent on the completeness and accuracy of the data. CDC and CMS work closely and are fully committed to ensuring complete and accurate reporting, which are critical for protecting patients and guiding national, state, and local prevention priorities. CMS collects some HAI data and healthcare personnel influenza vaccination summary data, which is done on a voluntary basis as part of its Fee-for-Service Medicare quality reporting programs, while others may report data required by a federal mandate. Facilities that fail to report quality measure data are subject to partial payment reduction in the applicable Medicare Fee-for-Service payment system. CMS links their quality reporting to payment for Medicare-eligible acute care hospitals, inpatient rehabilitation facilities, long-term acute care facilities, oncology hospitals, inpatient psychiatric facilities, dialysis facilities, and ambulatory surgery centers. Facilities report HAI data and healthcare personnel influenza vaccination summary data to CMS via NHSN as part of CMS's quality reporting programs to receive full payment.

Many healthcare facilities, even in states without HAI reporting legislation, submit limited HAI data to NHSN voluntarily. NHSN's data collection updates continue to support the incentive programs managed by CMS. For example, survey questions support requirements for CMS' quality reporting programs. Additionally, CDC has collaborated with CMS on a voluntary National Nursing Home Quality Collaborative, which focuses on recruiting nursing homes to report HAI data to NHSN and to retain their continued participation.

NHSN was previously approved in December of 2020 for 5,943,401 responses; 1,321,991 burden hours, and is due to expire on December 31, 2023. The proposed changes in this new ICR include revisions to ten data collection forms. There are a total of 86 proposed data collection forms, but no new forms are being added at this time. The total estimated burden requested in this Revision is for 1,584,651 hours.

ESTIMATED ANNUAL BURDEN

Respondent type	Form number & name	Number of respondents	Number of responses per respondent	Average burden per response (hour)
U.S. Healthcare Facilities/NHSN Participants	57.100 NHSN Registration Form	2,000	1	5/60
	57.101 Facility Contact Information	2,000	1	10/60
	57.103 Patient Safety Component—Annual Hospital Survey.	6,765	1	90/60
	57.104 Facility Administrator Change Request Form.	800	1	5/60
	57.105 Group Contact Information	1,000	1	5/60
	57.106 Patient Safety Monthly Reporting Plan.	7,821	12	15/60
	57.108 Primary Bloodstream Infection (BSI)	5,775	5	38/60
	57.111 Pneumonia (PNEU)	1,800	2	30/60
	57.112 Ventilator-Associated Event	5,463	8	28/60
	57.113 Pediatric Ventilator-Associated Event (PedVAE).	334	1	30/60

ESTIMATED ANNUAL BURDEN—Continued

Respondent type	Form number & name	Number of respondents	Number of responses per respondent	Average burden per response (hour)
	57.114 Urinary Tract Infection (UTI)	6,000	5	20/60
	57.115 Custom Event	600	91	35/60
	57.116 Denominators for Neonatal Intensive Care Unit (NICU).	1,100	12	4/60
	57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC).	500	12	5/60
	57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA).	5,500	60	5/60
	57.120 Surgical Site Infection (SSI)	6,000	9	35/60
	57.121 Denominator for Procedure	6,000	602	10/60
	57.122 HAI Progress Report State Health Department Survey.	55	1	28/60
	57.123 Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables.	2,500	12	5/60
	57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables.	2,500	12	5/60
	57.125 Central Line Insertion Practices Adherence Monitoring.	500	213	25/60
	57.126 MDRO or CDI Infection Form	720	11	30/60
	57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring.	5,500	29	15/60
	57.128 Laboratory-identified MDRO or CDI Event.	4,800	79	20/60
	57.129 Adult Sepsis	50	250	25/60
	57.135 Late Onset Sepsis/Meningitis Denominator Form: Data Table for monthly electronic upload.	300	6	5/60
	57.136 Late Onset Sepsis/Meningitis Event Form: Data Table for Monthly Electronic Upload.	300	6	5/60
	57.137 Long-Term Care Facility Component—Annual Facility Survey.	17,700	1	120/60
	57.138 Laboratory-identified MDRO or CDI Event for LTCF.	1,998	24	20/60
	57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF.	1,998	12	20/60
	57.140 Urinary Tract Infection (UTI) for LTCF	339	36	35/60
	57.141 Monthly Reporting Plan for LTCF	2,011	12	5/60
	57.142 Denominators for LTCF Locations	339	12	35/60
	57.143 Prevention Process Measures Monthly Monitoring for LTCF.	130	12	5/60
	57.150 LTAC Annual Survey	620	1	82/60
	57.151 Rehab Annual Survey	1,340	1	82/60
	57.200 Healthcare Personnel Safety Component Annual Facility Survey.	50	1	480/60
	57.204 Healthcare Worker Demographic Data.	50	200	20/60
	57.205 Exposure to Blood/Body Fluids	50	50	60/60
	57.206 Healthcare Worker Prophylaxis/Treatment.	50	30	15/60
	57.207 Follow-Up Laboratory Testing	50	50	15/60
	57.210 Healthcare Worker Prophylaxis/Treatment-Influenza.	50	50	10/60
	57.300 Hemovigilance Module Annual Survey.	500	1	85/60
	57.301 Hemovigilance Module Monthly Reporting Plan.	500	12	60/60
	57.303 Hemovigilance Module Monthly Reporting Denominators.	500	12	70/60
	57.305 Hemovigilance Incident	500	10	10/60
	57.306 Hemovigilance Module Annual Survey—Non-acute care facility.	500	1	35/60
	57.307 Hemovigilance Adverse Reaction—Acute Hemolytic Transfusion Reaction.	500	4	20/60
	57.308 Hemovigilance Adverse Reaction—Allergic Transfusion Reaction.	500	4	20/60

ESTIMATED ANNUAL BURDEN—Continued

Respondent type	Form number & name	Number of respondents	Number of responses per respondent	Average burden per response (hour)
	57.309 Hemovigilance Adverse Reaction—Delayed Hemolytic Transfusion Reaction.	500	1	20/60
	57.310 Hemovigilance Adverse Reaction—Delayed Serologic Transfusion Reaction.	500	2	20/60
	57.311 Hemovigilance Adverse Reaction—Febrile Non-hemolytic Transfusion Reaction.	500	4	20/60
	57.312 Hemovigilance Adverse Reaction—Hypotensive Transfusion Reaction.	500	1	20/60
	57.313 Hemovigilance Adverse Reaction—Infection.	500	1	20/60
	57.314 Hemovigilance Adverse Reaction—Post Transfusion Purpura.	500	1	20/60
	57.315 Hemovigilance Adverse Reaction—Transfusion Associated Dyspnea.	500	1	20/60
	57.316 Hemovigilance Adverse Reaction—Transfusion Associated Graft vs. Host Disease.	500	1	20/60
	57.317 Hemovigilance Adverse Reaction—Transfusion Related Acute Lung Injury.	500	1	20/60
	57.318 Hemovigilance Adverse Reaction—Transfusion Associated Circulatory Overload.	500	2	20/60
	57.319 Hemovigilance Adverse Reaction—Unknown Transfusion Reaction.	500	1	20/60
	57.320 Hemovigilance Adverse Reaction—Other Transfusion Reaction.	500	1	20/60
	57.400 Outpatient Procedure Component—Annual Facility Survey.	700	1	10/60
	57.401 Outpatient Procedure Component—Monthly Reporting Plan.	700	12	15/60
	57.402 Outpatient Procedure Component Same Day Outcome Measures.	200	1	40/60
	57.403 Outpatient Procedure Component—Monthly Denominators for Same Day Outcome Measures.	200	400	40/60
	57.404 Outpatient Procedure Component—SSI Denominator.	700	100	40/60
	57.405 Outpatient Procedure Component—Surgical Site (SSI) Event.	700	5	40/60
	57.500 Outpatient Dialysis Center Practices Survey.	7,200	1	12/60
	57.501 Dialysis Monthly Reporting Plan	7,200	12	5/60
	57.502 Dialysis Event	7,200	30	25/60
	57.503 Denominator for Outpatient Dialysis ..	7,200	30	10/60
	57.504 Prevention Process Measures Monthly Monitoring for Dialysis.	1,730	12	75/60
	57.505 Dialysis Patient Influenza Vaccination	615	50	10/60
	57.506 Dialysis Patient Influenza Vaccination Denominator.	615	5	10/60
	57.507 Home Dialysis Center Practices Survey.	430	1	30/60
	Weekly Healthcare Personnel Influenza Vaccination Cumulative Summary for Non-Long-Term Care Facilities.	125	52	60/60
	Weekly Healthcare Personnel Influenza Vaccination Cumulative Summary for Long-Term Care Facilities.	1,200	52	60/60
	Weekly Resident Influenza Vaccination Cumulative Summary for Long-Term Care Facilities.	2,500	52	60/60
	Annual Healthcare Personnel Influenza Vaccination Summary.	5,000	1	120/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–28031 Filed 12–23–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting of the Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board). This meeting is open to the public, buy without a public comment period. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcomed to listen to the meeting by joining the teleconference (information below). The audio conference line has 150 ports for callers.

DATES: The meeting will be held on February 16, 2022, from 11:00 a.m. to 1:00 p.m., EST. Written comments must be received on or before February 9, 2022.

ADDRESSES: You may submit comments by mail to: Sherri Diana, National Institute for Occupational Safety and Health, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226. *Meeting Information:* Audio Conference Call via FTS Conferencing. The USA toll-free dial-in number is 1–866–659–0537; the pass code is 9933701.

FOR FURTHER INFORMATION CONTACT: Rashaun Roberts, Ph.D., Designated Federal Officer, NIOSH, CDC, 1090 Tusculum Avenue, Mailstop C–24, Cincinnati, Ohio 45226, Telephone: (513) 533–6800, Toll Free: 1(800)CDC–INFO, Email: *ocas@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines which have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC.

The Advisory Board's charter was issued on August 3, 2001, renewed at appropriate intervals, rechartered on March 22, 2020, and will terminate on March 22, 2022.

Purpose: The Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters to be Considered: The agenda will include discussions on: Work Group and Subcommittee Reports; Update on the Status of SEC Petitions; and plans for the April 2022 Advisory Board meeting. Agenda items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–28020 Filed 12–23–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH), Subcommittee on Procedures Reviews (SPR), National Institute for Occupational Safety and Health (NIOSH)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Subcommittee on Procedures Reviews (SPR) of the Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board). This meeting is open to the public, but without a public comment period. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcomed to listen to the meeting by joining the audio conference (information below). The audio conference line has 150 ports for callers.

DATES: The meeting will be held on February 15, 2022, from 11:00 a.m. to 3:30 p.m., EST. Written comments must be received on or before February 8, 2022.

ADDRESSES: You may submit comments by mail to: Sherri Diana, National Institute for Occupational Safety and Health, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226.

Meeting Information: Audio Conference Call via FTS Conferencing. The USA toll-free dial-in number is 1–866–659–0537; the pass code is 9933701.

FOR FURTHER INFORMATION CONTACT: Rashaun Roberts, Ph.D., Designated Federal Officer, NIOSH, CDC, 1090 Tusculum Avenue, Mailstop C–24, Cincinnati, Ohio 45226, Telephone: (513) 533–6800, Toll Free 1 (800) CDC–INFO, Email: *ocas@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC.

The Advisory Board's charter was issued on August 3, 2001, renewed at appropriate intervals, and rechartered under Executive Order 13889 on March 22, 2020, and will terminate on March 22, 2022.

Purpose: The Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. SPR is responsible for overseeing, tracking, and participating in the reviews of all procedures used in the dose reconstruction process by the NIOSH Division of Compensation Analysis and Support (DCAS) and its dose reconstruction contractor (Oak Ridge Associated Universities—ORAU).

Matters To Be Considered: The agenda will include discussions on the following dose reconstruction procedures: (a) Procedures associated specifically with the following sites: Birdsboro Steel, Peek Street facility, and Savannah River Site (SRS), (b) procedures associated with Atomic Weapons Employers generally; and, (c) general procedures for dose reconstructions. Agenda items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–28021 Filed 12–23–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Annual Report on Households Assisted by the Low Income Home Energy Assistance Program (LIHEAP) (OMB #0970–0060)

AGENCY: Office of Community Services, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Community Services (OCS), Division of Energy Assistance, is requesting a 3-year extension of the Household Report Form (OMB #0970–0060, expiration February 28, 2022). Submission of the completed report is one requirement for LIHEAP grant recipients applying for federal LIHEAP block grant funds. OCS proposes minor changes related to reporting of supplemental funding and to update reporting dates and number of respondents.

DATES: Comments may be submitted through February 25, 2022. In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: States, the District of Columbia, and the Commonwealth of Puerto Rico are required by the Low-Income Energy Assistance Act of 1981 (42 U.S.C. 8624, Sec 2610) to report statistics for the previous federal fiscal year (FFY) on the following:

- Assisted and applicant households, by type of LIHEAP assistance and funding source;
- Assisted households receiving nominal payments of $50 or less, by funding source;
- Assisted households receiving only utility payment assistance, by funding source; this information will automatically be transferred to the grant recipient's Performance Data Form;
- Assisted households, regardless of the type(s) of LIHEAP assistance or funding source, excluding households that only receive nominal payments of $50 or less;
- Assisted households, by type of LIHEAP assistance and funding source, having at least one vulnerable member who is at least 60 years or older, disabled, or 5 years old or younger;
- Assisted households, by type of LIHEAP assistance and funding source, with at least one member age 2 years or under;
- Assisted households, by type of LIHEAP assistance and funding source, with at least one member ages 3 years through 5 years; and
- Assisted households, regardless of the type(s) of LIHEAP assistance or funding source, having at least one member 60 years or older, disabled, or 5 years old or younger.

Indian tribal grant recipients are required to submit data only on the number of households, by funding source, receiving heating, cooling, energy crisis, and/or weatherization benefits.

In FFY 2020, OCS updated the form to allow for the reporting of households served by separate LIHEAP funding types and benefits provided by the following: (1) Funds from regular LIHEAP FFY appropriations acts, including any Continuing Resolutions and final appropriations acts, reallotted prior year funds, and federal LIHEAP funds carried-over to or expended in the current year; (2) supplemental funds from the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) (Pub. L. 116–136); and (3) funds from any subsequent supplemental LIHEAP appropriations acts. ACF proposes similar changes to the report for FFY 2022, including the addition of lines that allow for the reporting of households served by LIHEAP funds from the American Rescue Plan Act of 2021 (Pub. L. 117–2). OCS has also

updated the request to reflect the current number of expected respondents and appropriate reporting dates.

The information is being collected for the Department's annual LIHEAP Report to Congress. The data also provides information about the need for LIHEAP funds. Finally, the data are used in the calculation of LIHEAP performance measures under the Government Performance and Results Act of 1993. The data elements will allow the accuracy of measuring LIHEAP targeting performance and LIHEAP cost efficiency.

Respondents: State governments, tribal governments, U.S. territories, and the District of Columbia.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Assisted Household Report-Long Form	56	1	43	2,408
Assisted Household Report-Short Form	151	1	2	302

Estimated Total Annual Burden Hours: 2,710.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) 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 through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted through February 25, 2022.

Authority: 42 U.S.C. 8629 and 45 CFR 96.92.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–28125 Filed 12–22–21; 11:15 am]

BILLING CODE 4184–80–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; National Directory of New Hires (OMB No. 0970–0166)

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF), is requesting the federal Office of Management and Budget (OMB) to approve the National Directory of New Hires (NDNH), with minor changes to the Multistate Employer Registration form, for an additional three years. The current OMB approval expires July 31, 2022.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The NDNH is a federally mandated repository of employment and wage information. The information maintained in the NDNH is collected electronically and is used for authorized purposes. State child support agencies use the NDNH information to locate a parent living or working in a different state and to take appropriate interstate actions to establish, modify, or enforce a child support order. NDNH information is also used for authorized purposes by specific state and federal agencies to help administer certain programs, prevent overpayments, detect fraud, assess benefits, and recover funds, as provided under 42 U.S.C. 653(i)(1).

Respondents: Employers, State Child Support Agencies, and State Workforce Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average annual burden hours per response	Total annual burden hours
New Hire: Employers Reporting Manually	5,411,180	1.29	.025	174,510.56
New Hire: Employers Reporting Electronically	664,757	94.77	.00028	17,639.73
New Hire: States	54	129,629.63	.017	119,000.00
Quarterly Wage (QW) & Unemployment Insurance (UI)	53	28.00	.00028	0.42
Multistate Employer Registration Form	1,118	1.00	.05	55.90

Estimated Total Annual Burden Hours: 311,207.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) 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 through the use of automated collection techniques or other forms of information technology. Consideration will be given

to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 653A(b)(1)(A) and (B); 42 U.S.C. 653A(g)(2)(A); 26 U.S.C. 3304(a)(16)(B); 42 U.S.C. 503(h)(1)(A); and 42 U.S.C. 653A(g)(2)(B).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–28065 Filed 12–23–21; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Children's Bureau National Youth in Transition Database (NYTD) (OMB #0970–0340)

AGENCY: Children's Bureau, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the National Youth in Transition Database (NYTD) Youth Services Report and Youth Outcomes Survey Data Collection (OMB #0970–0340, expiration date 03/31/2022). There are no changes requested to the form.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Foster Care Independence Act of 1999 (42 U.S.C. 1305 *et seq.*) as amended by Public Law 106–169 requires state child welfare agencies to collect and report to the ACF Children's Bureau data on the characteristics of youth receiving independent living services and information regarding their outcomes. The regulation implementing NYTD, listed in 45 CFR 1356.80, contains standard data collection and reporting requirements for states to meet the law's requirements. Additionally, the Family First Prevention Services Act of 2017 (H.R. 253) further outlines the expectation of the collection and reporting of data and outcomes regarding youth who are in receipt of independent living services. ACF uses the information collected under the regulation to track independent living services, assess the collective outcomes of youth, and potentially to evaluate state performance with regard to those outcomes consistent with the law's mandate.

Respondents: State agencies that administer the Chafee Foster Care Program for Successful Transition to Adulthood (Chafee program) and youth served by these agencies.

ANNUAL BURDEN ESTIMATES FOR 2022–2024

Information collection title	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours for 2022–24	Annual burden hours
State Data File	52	2	3916	407,264	135,755
Youth Outcomes Survey	47,000	1	.5	23,500	7,833
Estimated Annual Burden Total					143,588

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) 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 through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: NYTD is authorized by Public Law 106–169, enacted December 14, 1999. This public law establishes the John H. Chafee Foster Care Independence Program, now known as Chafee program, at section 477 of the Social Security Act. NYTD data is collected pursuant to 45 CFR 1356.80.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–28058 Filed 12–23–21; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0367]

Compliance Policy Guide Sec. 540.525 Scombrotoxin (Histamine)-Forming Fish and Fishery Products—Decomposition and Histamine; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft Compliance Policy Guide entitled ''Sec. 540.525 Scombrotoxin (Histamine)-forming Fish and Fishery Products—Decomposition and Histamine.'' The draft guidance, when finalized, will replace existing guidance for FDA staff on adulteration associated with decomposition and histamine identified during surveillance sampling and testing of fish and fishery products susceptible to histamine formation.

DATES: Submit either electronic or written comments on the draft guidance by February 25, 2022 to ensure that we consider your comment on the draft guidance before we begin 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–2021–D–0367 for ''Sec. 540.525 Scombrotoxin (Histamine)-forming Fish and Fishery Products—Decomposition and Histamine (CPG 7108.24).'' 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.'' We will review this copy, including the claimed confidential information, in our 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 draft guidance to Division of Seafood Safety (HFS–325), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Steven Bloodgood, Division of Seafood Safety (HFS–325), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–5316, email: *steven.bloodgood@fda.hhs.gov;* or Jessica Larkin, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft Compliance Policy Guide (CPG) entitled ''Sec. 540.525 Scombrotoxin (Histamine)-forming Fish and Fishery Products—Decomposition and Histamine (CPG 7108.24).'' This draft CPG would update and replace existing guidance for FDA staff on adulteration associated with decomposition and histamine identified during surveillance sampling and testing of fish and fishery products susceptible to scombrotoxin (histamine) formation. The draft CPG would revise FDA regulatory action guidance for sensory analysis and/or histamine levels in scombrotoxin-forming fish and fishery products.

We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: December 21, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–28053 Filed 12–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1252]

Panray Corp. Sub Ormont Drug and Chemical Co., Inc., et al.; Proposal To Withdraw Approval of Three New Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is proposing to withdraw approval of three new drug applications (NDAs) and is announcing an opportunity for the NDA holders to

request a hearing on this proposal. The basis for the proposal is that the NDA holders have repeatedly failed to file required annual reports for those NDAs.

DATES: The NDA holders may submit a request for a hearing by January 26, 2022. Submit all data, information, and analyses upon which the request for a hearing relies February 25, 2022. Submit electronic or written comments by February 25, 2022.

ADDRESSES: The request for a hearing may be submitted by the NDA holders by either of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments to submit your request for a hearing. Comments submitted electronically to *https://www.regulations.gov,* including any attachments to the request for a hearing, will be posted to the docket unchanged.

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.
- Because your request for a hearing will be made public, you are solely responsible for ensuring that your request 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. The request for a hearing must include the Docket No. FDA–2021–N–1252 for ''Panray Corp. Sub Ormont Drug and Chemical Co., Inc., et al.; Proposal To Withdraw Approval of Three New Drug Applications; Opportunity for a Hearing.'' The request for a hearing will be placed in the docket and 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.

The NDA holders may submit all data and analyses upon which the request for a hearing relies in the same manner as the request for a hearing except as follows:

- Confidential Submissions—To submit any data analyses with confidential information that you do not wish to be made publicly available, submit your data and analyses only as a written/paper submission. You should submit two copies total of all data and analyses. 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 any decisions on this matter. 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* or available at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Submit both copies to the Dockets Management Staff. Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law.

Comments Submitted by Other Interested Parties: For all comments submitted by other interested parties, submit comments 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–2021–N–1252 for ''Panray Corp. Sub Ormont Drug and Chemical Co., Inc., et al.; Proposal To Withdraw Approval of Three New Drug Applications; Opportunity for a Hearing.'' Received comments, those filed in a timely manner (see **DATES**, 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.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The holder of an approved NDA to market a new drug for human use is required to submit annual reports to FDA concerning its approved NDA under §§ 314.81 and 314.98 (21 CFR 314.81 and 314.98). The holders of the approved NDAs listed in Table 1 have repeatedly failed to submit the required annual reports and have not responded to the Agency's request for submission of the reports.

TABLE 1—APPROVED NDAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED

Application No.	Drug	NDA holder
NDA 008284	Cortisone Acetate Tablets, 5 milligrams (mg) and 25 mg	Panray Corp. Sub Ormont Drug and Chemical Co., Inc., 520 South Dean St., Englewood, NJ 07631.
NDA 009659	Hydrocortisone Tablets, 10 mg and 20 mg	Do.
NDA 019503	Triamcinolone Acetonide Suspension, 3 mg/milliliters (mL)	Parnell Pharmaceuticals Inc., 111 Francisco Blvd., San Rafael, CA 94901.

Therefore, notice is given to the holders of the approved NDAs listed in table 1 and to all other interested persons that the Director of CDER proposes to issue an order, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)), withdrawing approval of the NDAs and all amendments and supplements thereto on the grounds that the NDA holders have failed to submit reports required under § 314.81.

In accordance with section 505 of the FD&C Act and 21 CFR part 314, the NDA holders are hereby provided an opportunity for a hearing to show why the approval of the NDAs listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these NDAs.

An NDA holder who decides to seek a hearing must file the following: (1) A written notice of participation and request for a hearing (see **DATES** and **ADDRESSES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see **DATES** and **ADDRESSES**). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, the information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 (21 CFR 314.200) and in 21 CFR part 12.

The failure of an NDA holder to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that NDA holder not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the NDAs and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the NDAs, and the drug products may not thereafter be lawfully introduced or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All paper submissions under this notice of opportunity for a hearing must be filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.*

This notice is issued under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

Dated: December 20, 2021.

Jacqueline Corrigan-Curay,

Principal Deputy Center Director, Center for Drug Evaluation and Research.

[FR Doc. 2021–27946 Filed 12–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1118]

Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia; 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 a final guidance entitled ''Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH).'' This guidance identifies the key features of non-clinical and clinical investigational plans used to support investigational device exemption applications, premarket approval applications, De Novo classification requests, and some premarket notification submissions for devices used in the treatment of BPH.

DATES: The announcement of the guidance is published in the **Federal Register** on December 27, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2020–D–1118 for ''Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH).'' 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 guidance document entitled ''Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)'' to the Office of Policy, Guidance and Policy Development, 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: Charles Viviano, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2680, Silver Spring, MD 20993–0002, 240–402–2975.

SUPPLEMENTARY INFORMATION:

I. Background

As men age, the prostate enlarges over time, obstructing the prostatic urethra and resulting in anatomic and functional changes in the bladder. The resulting condition, known as benign prostatic hyperplasia (BPH), can be associated with decreased peak urinary flow rate and increased post void residual urine. Men with BPH experience bothersome lower urinary tract symptoms that affect their quality of life by disrupting sleep patterns or interfering with daily activities.

This guidance revises the guidance entitled ''Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH) [1],'' issued on August 17, 2010 (''2010 BPH guidance''). This guidance identifies the key features of non-clinical and clinical investigational plans used to support investigational device exemption applications, premarket approval applications, De Novo classification requests, and some premarket notification submissions for devices used in the treatment of BPH. Some recommendations in this document may not apply to a particular device, and additional recommendations may be appropriate for novel device types or technologies. FDA will consider alternative non-clinical and clinical testing when the proposed alternatives are supported by an adequate scientific rationale.

FDA issued a draft guidance entitled ''Select Updates for Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH) [2],'' which proposed to add new devices within scope and updates to the animal and clinical studies sections of the 2010 BPH guidance. A notice of availability of the draft guidance appeared in the **Federal Register** of July 14, 2020 (85 FR 42406). FDA considered comments received and revised the guidance as appropriate in response to the comments, including the following technical changes: Suggested examination of surrounding anatomy during animal studies for embolic devices; clarification of sexual function; additional specificity around the primary safety endpoint; inclusion of secondary endpoints such as return to normal activities; measuring prostate volume according to current clinical guidelines; additional post-treatment evaluation; and consideration of the addition or increase in medications or other modalities as treatment failure. The remainder of the content of the 2010 BPH guidance remains largely unchanged.

This guidance is being issued consistent with FDA's good guidance

[1] Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-non-clinical-and-clinical-investigation-devices-used-treatment-benign-prostatic-hyperplasia.*

[2] Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-guidance-non-clinical-and-clinical-investigation-devices-used-treatment-benign.*

practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on non-clinical and clinical investigation of devices used for the treatment of BPH. 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 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 at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1724 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions	0910–0756
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards.	0910–0755
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910–0119

Dated: December 20, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27919 Filed 12–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2330]

Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers; 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 final guidance for industry entitled ''Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers.'' This guidance represents FDA's current thinking on the management and conduct of pathology peer review performed during good laboratory practice (GLP)-compliant toxicology studies. This guidance finalizes the draft guidance ''Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers'' issued on September 30, 2019. This revision includes editorial changes to improve the clarity of the document.

DATES: The announcement of the guidance is published in the **Federal Register** on December 27, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2019–D–2330 for ''Pathology Peer Review in Nonclinical Toxicology

Studies: Questions and Answers.'' 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 this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Tahseen Mirza, Office of Study Integrity and Surveillance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2211, Silver Spring, MD 20993, 301–796–7645; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911; Judy Davis, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1216, Silver Spring, MD 20993, 301–796–6636; Hilary Hoffman, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rm. 389, Rockville, MD 20855, 240–402–8406; Yuguang Wang, Office of the Center Director, Center for Food Safety and Nutrition, Food and Drug Administration, 5001 Campus Dr., Rm. 4A035, College Park, MD 20740, 240–402–1757; Hans Rosenfeldt, Office of Science, Center for Tobacco Products, Food and Drug Administration, 11785 Beltsville Dr., Bldg. BELT1, Rm. 5322, Beltsville, MD 20705–3121, 301–796–2202; or Tony Taube, Division of Operational Policy, Office of Regulatory Affairs, 12420 Parklawn Dr., Rm. 4044, Rockville, MD 20857 email: *ORAPolicyStaffs@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers.'' This guidance represents FDA's current thinking on the management and conduct of pathology peer review performed during GLP-compliant toxicology studies.

The histopathological assessment of tissue samples is one of the key activities performed during GLP-compliant toxicology studies. Commonly, histopathological assessment includes an initial read of tissue slides by the study pathologist and a subsequent review (referred to as pathology peer review) by a second pathologist. Pathology peer review may be particularly useful in situations where unique or unexpected findings are noted or when the peer-review pathologist has a particular expertise relevant to the study. When pathology peer review occurs as part of a nonclinical study conducted in compliance with GLP regulations, it should be well-documented. However, documentation practices during pathology peer review have not been clearly defined and vary among nonclinical testing facilities.

Although the current regulations include general requirements for histopathology evaluation (for example, it requires that standard operating procedures be established to cover histopathology), pathology peer review is not specifically addressed in the current regulations. This Q&A document is intended to clarify FDA's recommendations concerning the management and conduct of pathology peer review performed during GLP-compliant toxicology studies.

This guidance finalizes the draft guidance entitled ''Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers'' issued on September 30, 2019 (84 FR 37646). FDA considered comments received on the draft guidance as the guidance was finalized. Editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers.'' 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 58 (Good Laboratory Practice for Non-Clinical Laboratory Studies) have been approved under OMB control number 0910–0119; and submission of information for FDA review under an investigational new drug application for human drug or

biologic products is approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

Dated: December 21, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–28051 Filed 12–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes And Digestive and Kidney Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meetings 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 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 Diabetes and Digestive and Kidney Diseases Advisory Council.

Date: May 11–12, 2022.

Open: May 11, 2022, 10:00 a.m. to 1:30 p.m.

Agenda: To present the Director's Report and other scientific presentations.

Place: National Institutes of Health Building 31, C-Wing 6th Floor Conference Center, Conference Rooms C, D&E, and F&G, 31 Center Drive, Bethesda, MD 20892.

Closed: May 12, 2022, 1:30 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Building 31, C-Wing 6th Floor Conference Center, Conference Rooms C, D&E, and F&G, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Karl F. Malik, Ph.D., Director Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council Diabetes, Endocrinology and Metabolic Diseases Subcommittee.

Date: May 11–12, 2022.

Open: May 12, 2022, 10:00 a.m. to 11:30 a.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health Building 31, C-Wing 6th Floor Conference Center, Conference Rooms C, D&E, and F&G, 31 Center Drive Bethesda, MD 20892.

Closed: May 12, 2022, 11:45 a.m. to 1:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Building 31 Conference Rooms C, D&E, and F&G 31 Center Drive Bethesda, MD 20892.

Contact Person: Karl F. Malik, Ph.D., Director Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council Digestive Diseases and Nutrition Subcommittee.

Date: May 11–12, 2022.

Open: May 12, 2022, 10:00 a.m. to 11:30 a.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health Building 31, C-Wing 6th Floor Conference Center, Conference Rooms C, D&E, and F&G, 31 Center Drive Bethesda, MD 20892.

Closed: May 12, 2022, 11:45 a.m. to 1:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Building 31 Conference Rooms C, D&E, and F&G 31 Center Drive Bethesda, MD 20892.

Contact Person: Karl F. Malik, Ph.D., Director Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council Kidney, Urologic and Hematologic Diseases Subcommittee.

Date: May 11–12, 2022.

Open: May 12, 2022, 10:00 a.m. to 12:00 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health Building 31, C-Wing 6th Floor Conference Center, Conference Rooms C, D&E, and F&G, 31 Center Drive Bethesda, MD 20892.

Closed: May 12, 2022, 12:15 p.m. to 1:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Building 31, C-Wing 6th Floor Conference Center, Conference Rooms C, D&E, and F&G, 31 Center Drive Bethesda, MD 20892.

Contact Person: Karl F. Malik, Ph.D., Director Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this 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 instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors 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: *www.niddk.nih.gov/fund/divisions/DEA/Council/coundesc.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS).

Dated: December 20, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–28000 Filed 12–23–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) 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 Aging Special Emphasis Panel; Gut microbiome/metabolites in Stroke and Dementia.

Date: January 27, 2022.

Time: 12:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Video Meeting).

Contact Person: Joshua Jin-Hyouk Park, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 496–6208 *joshua.park4@nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Targeting Astrocytes in AD and ADRD.

Date: February 15, 2022.

Time: 12:30 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging Gateway Building 7201 Wisconsin Avenue Bethesda, MD 20892 (Video Meeting).

Contact Person: Joshua Jin-Hyouk Park, Ph.D., Scientific Review Officer, Scientific Review Branch,National Institute on Aging, National Institutes of Health, Gateway Building 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 496–6208 *joshua.park4@nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Neuroimmunology of AD and CAA in lymphatics.

Date: February 17, 2022.

Time: 12:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Video Meeting).

Contact Person: Joshua Jin-Hyouk Park, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 496–6208, *joshua.park4@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 20, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–28001 Filed 12–23–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council, which was published in the **Federal Register** on November 09, 2021, FR Doc 2021–24439, 86 FR 62187.

The meeting notice is amended to change the time from 10:00 a.m.–1:45 p.m., to 10:00 a.m.–2:00 p.m. The meeting is partially Closed to the public.

Dated: December 20, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–28002 Filed 12–23–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

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 Institute of Allergy and Infectious Diseases Special Emphasis Panel; Systems Approach to Understand Mechanisms of Heterogeneous Response to Influenza (R01 Clinical Trial Not Allowed).

Date: January 21, 2022.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F21B, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Maryam Feili-Hariri, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F21B, Rockville, MD 20852, 240–669–5026, *haririmf@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 20, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–28004 Filed 12–23–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Fogarty International Center Advisory Board.

The meeting will be open to the public via online meeting. 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 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: Fogarty International Center Advisory Board.

Date: February 7–8, 2022.

Closed: February 7, 2022, 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate the second level of grant applications.

Place: Fogarty International Center National Institutes of Health, 31 Center Drive, Room B2C02, Bethesda, MD 20892 (Virtual Meeting).

Open: February 8, 2022, 12:00 p.m. to 3:00 p.m.

Agenda: Update and discussion of current and planned Fogarty International Center activities.

Place: Fogarty International Center National Institutes of Health, 31 Center Drive, Room B2C02, Bethesda, MD 20892 (Virtual Meeting).

Meeting Access: https://www.fic.nih.gov/About/Advisory/Pages/default.aspx.

Contact Person: Kristen Weymouth, Executive Secretary, Fogarty International Center, National Institutes of Health, 31 Center Drive, Room B2C02, Bethesda, MD 20892, 301–496–1415, *kristen.weymouth@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.fic.nih.gov/About/Advisory/Pages/default.aspx,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.106, Minority International Research Training Grant in the Biomedical and Behavioral Sciences; 93.154, Special International Postdoctoral Research Program in Acquired Immunodeficiency Syndrome; 93.168, International Cooperative Biodiversity Groups Program; 93.934, Fogarty International Research Collaboration Award; 93.989, Senior International Fellowship Awards Program, National Institutes of Health, HHS)

Dated: December 20, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–28006 Filed 12–23–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS–NIH–CDC–SBIR PHS 2022–1 Phase I: Development of Rapid POC Diagnostics for Treponema pallidum (Topic 108).

Date: January 20, 2022.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E6, Rockville, MD 20892, (Virtual Meeting).

Contact Person: Ann Marie M. Brighenti, Ph.D., Scientific Review Officer, Scientific Review Program, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E6, Rockville, MD 20852, 301–761–3100, *AnnMarie.Cruz@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 20, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–28003 Filed 12–23–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel HHS–NIH–CDC–SBIR PHS 2022–1 Phase II: Development of monoclonal antibody-mediated interventions to combat malaria (Topic 109).

Date: January 19, 2022.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G74, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Hailey Weerts, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G74, Rockville, MD 20852, (240) 669–5931, *weertshp@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel HHS–NIH–CDC–SBIR PHS 2022–1 Phase I: Development of monoclonal antibody-mediated interventions to combat malaria (Topic 109).

Date: January 19, 2022.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G74, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Hailey Weerts, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G74, Rockville, MD 20852, (240) 669–5931, *weertshp@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS).

Dated: December 20, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–27992 Filed 12–23–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0140]

Collection of Advance Information From Certain Undocumented Individuals on the Land Border

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments; reinstatement with change of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border

Protection 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 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than January 26, 2022) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice 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.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (Volume 86 FR Page 53667) on September 28, 2021, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) 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; (2) 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) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions 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 submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Collection of Advance Information from Certain Undocumented Individuals on the Land Border.

OMB Number: 1651–0140.

Form Number: N/A.

Current Actions: Reinstatement with change.

Type of Review: Reinstatement with change.

Affected Public: Individuals.

Abstract: The Department of Homeland Security (DHS), in consultation with U.S. Customs and Border Protection (CBP), has established a process to streamline the processing of undocumented noncitizens under Title 8 of the United States Code at certain ports of entry (POEs), as these individuals require secondary processing upon their arrival, which takes longer than when individuals arrive with sufficient travel documentation.

CBP is proposing extending and amending this data collection, which was established on an emergency basis on May 3, 2021. This data collection expands on the previous collection process for persons who may warrant an exception to the CDC's *Order Suspending the Right To Introduce Certain Persons from Countries Where a Quarantinable Communicable Disease Exists* (''CDC Order'') (85 FR 65806), to include undocumented noncitizens who will be processed under Title 8 at the time they arrive at the POE after the CDC Order is rescinded, in whole or in part. The purpose is to continue to achieve efficiencies to process undocumented noncitizens under Title 8 upon their arrival at the POE, consistent with public health protocols, space limitations, and other restrictions.

CBP collects certain biographic and biometric information from undocumented noncitizens prior to their arrival at a POE, to streamline their processing at the POE. The requested information is that which CBP would otherwise collect from these individuals during primary and/or secondary processing. This information is voluntarily provided by undocumented noncitizens, directly or through non-governmental organizations (NGOs) and international organizations (IOs). Providing this information is not a prerequisite for processing under Title 8, but reduces the amount of data entered by CBP Officers (CBPOs) and the length of time an undocumented noncitizen remains in CBP custody.

The biographic and biometric information being collected in advance, that would otherwise be collected during primary and/or secondary processing at the POEs includes, but is not limited to, descriptive information such as: Name, Date of Birth, Country of Birth, City of Birth, Country of Residence, Contact Information, Addresses, Nationality, Employment history (optional), Travel history, Emergency Contact (optional), U.S. and foreign addresses, Familial Information (optional), Marital Status (optional), Identity Document (not a Western Hemisphere Travel Initiative (WHTI) compliant document) (optional), Gender, Preferred Language, Height, Weight, Eye color and Photograph.

This information is submitted to CBP by undocumented noncitizens (directly or through NGOs and IOs) on a voluntary basis, for the purpose of facilitating and implementing CBP's mission. This collection is consistent with DHS' and CBP's authorities, including under 6 U.S.C. 202 and 211(c). Pursuant to these sections, DHS and CBP are generally charged with ''[s]ecuring the borders, territorial waters, ports, terminals, waterways, and air, land, and sea transportation systems of the United States,'' and ''implement[ing] screening and targeting capabilities, including the screening, reviewing, identifying, and prioritizing of passengers and cargo across all international modes of transportation, both inbound and outbound.''

Proposed Changes:

This information collection is being changed to require the submission of the photograph—previously optional—for all who choose to provide advance information. The submission of a photograph in advance will provide CBPOs with a mechanism to match a noncitizen who arrives at the POE with the photograph submitted in advance, therefore identifying those individuals, and verifying their identity. The photograph is particularly important for identity verification once NGOs/IOs are no longer facilitating the presentation of all individuals for CBP processing (NGOs/IOs will be able to continue

assisting for some individuals but others will be able to participate on their own).

CBP will also allow individuals to request to present themselves for processing at a specific POE on a specific day and time, although such a request does not guarantee that an individual will be processed at a given time. Individuals will have the opportunity to modify their requests within the CBP One™ application to an alternate day or time. In all cases, CBP will inspect, and process individuals based on available capacity at the POE. This new functionality does not require the collection of new Personal Identifiable Information (PII) data elements.

Type of Information Collection: Advance Information on Undocumented Travelers.

Estimated Number of Respondents: 91,250.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 91,250.

Estimated Time per Response: 16 minutes.

Estimated Total Annual Burden Hours: 24,333.

Dated: December 21, 2021.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2021–28005 Filed 12–23–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2021–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below. The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP).

DATES: The date of March 22, 2022 has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *https://msc.fema.gov* by the date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Imperial County, California and Incorporated Areas Docket No.: FEMA–B–2075	
Unincorporated Areas of Imperial County	Imperial County Planning and Development Services, 801 Main Street, El Centro, CA 92243.
Riverside County, California and Incorporated Areas Docket No.: FEMA–B–2075	
Unincorporated Areas of Riverside County	Riverside County Flood Control and Water Conservation District, 1995 Market Street, Riverside, CA 92501.

Community	Community map repository address
San Diego County, California and Incorporated Areas Docket No.: FEMA–B–2075	
Unincorporated Areas of San Diego County	Department of Public Works Flood Control, 5510 Overland Avenue, Suite 410 MS 0326, San Diego, CA 92123.
Glades County, Florida and Incorporated Areas Docket No.: FEMA–B–2074	
Unincorporated Areas of Glades County	Glades County Community Development Department, 198 6th Street, Moore Haven, FL 33471.
Chase County, Kansas and Incorporated Areas Docket No.: FEMA–B–2061	
City of Cedar Point	City Hall, 127 Cedar Street, Cedar Point, KS 66843.
City of Cottonwood Falls	City Hall, 220 Broadway Street, Cottonwood Falls, KS 66845.
City of Elmdale	Chase County Courthouse, 300 Pearl Street, Cottonwood Falls, KS 66845.
City of Matfield Green	Chase County Courthouse, 300 Pearl Street, Cottonwood Falls, KS 66845.
City of Strong City	City Hall, 204 West Topeka Avenue, Strong City, KS 66869.
Unincorporated Areas of Chase County	Chase County Courthouse, 300 Pearl Street, Cottonwood Falls, KS 66845.

[FR Doc. 2021–28039 Filed 12–23–21; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2021–0002; Internal Agency Docket No. FEMA–B–2189]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: Comments are to be submitted on or before March 28, 2022.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–2189, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a

mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Caroline County, Virginia and Incorporated Areas Project: 19–03–0013S Preliminary Date: June 01, 2021	
Town of Bowling Green	Town Hall, 117 Butler Street, Bowling Green, VA 22427.
Town Port Royal	Town Hall, 419 King Street, Port Royal, VA 22535.
Unincorporated Areas of Caroline County	Caroline County Planning and Building Department, 233 West Broaddus Avenue, Bowling Green, VA 22427.
Spotsylvania County, Virginia (All Jurisdictions) Project: 18–03–0011S Preliminary Date: September 30, 2021	
Unincorporated Areas of Spotsylvania County	Spotsylvania County Planning and Zoning Department, 9019 Old Battlefield Boulevard, Suite 320, Spotsylvania, VA 22553.

[FR Doc. 2021–28037 Filed 12–23–21; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2021–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below. The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP).

DATES: The date of May 3, 2022 has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *https://msc.fema.gov* by the date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Nottoway County, Virginia and Incorporated Areas Docket No.: FEMA–B–2101	
Town of Blackstone	Town Hall, 100 West Elm Street, Blackstone, VA 23824.

Community	Community map repository address
Town of Burkeville	Town Hall, 224 2nd Street Northwest, Burkeville, VA 23922.
Town of Crewe	Town Office, 125 East Carolina Avenue, Crewe, VA 23930.
Unincorporated Areas of Nottoway County	Nottoway County Administrator's Offices, 344 West Courthouse Road, Nottoway, VA 23955.
Webster County, West Virginia and Incorporated Areas Docket No.: FEMA–B–2053	
Town of Camden-On-Gauley	Water Works Office, 9580 Webster Road, Camden-On-Gauley, WV 26208.
Unincorporated Areas of Webster County	Webster County Office of Emergency Services Building, 210 Back Fork Street, Webster Springs, WV 26288.

[FR Doc. 2021–28035 Filed 12–23–21; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2021–0002; Internal Agency Docket No. FEMA–B–2187]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: Comments are to be submitted on or before March 28, 2022.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–2187, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Archuleta County, Colorado and Incorporated Areas Project: 20–08–0040S Preliminary Date: January 18, 2021	
Southern Ute Indian Tribe	Southern Ute Indian Tribe Annex Building GIS Group, 116 Memorial Drive, Ignacio, CO 81137.
Unincorporated Areas of Archuleta County	Archuleta County Commissioner's Office, 398 Lewis Street, Pagosa Springs, CO 81147.
San Juan County, Colorado and Incorporated Areas Project: 20–08–0041S Preliminary Date: January 18, 2021	
Town of Silverton	Town Hall, 1360 Greene Street, Silverton, CO 81433.
Unincorporated Areas of San Juan County	San Juan County Courthouse, 1557 Greene Street, Silverton, CO 81433.
Cache County, Utah and Incorporated Areas Project: 16–08–0053S Preliminary Date: June 30, 2021	
City of Hyde Park	City Office, 113 East Center Street, Hyde Park, UT 84318.
City of Hyrum City	City Office, 60 West Main Street, Hyrum City, UT 84319.
City of Logan	Public Works, 290 North 100 West, Logan, UT 84321.
City of Mendon	City Office, 15 North Main Street, Mendon, UT 84325.
City of Millville	City Office, 510 East 300 South, Millville, UT 84326.
City of Nibley	City Office, 455 West 3200 South, Nibley, UT 84321.
City of Providence	City Hall, 164 North Gateway Drive, Providence, UT 84332.
City of Richmond	City Office, 90 South 100 West, Richmond, UT 84333.
City of River Heights	City Office, 520 South 500 East, River Heights, UT 84321.
City of Smithfield	City Office, 96 South Main Street, Smithfield, UT 84335.
City of Wellsville	City Office, 75 East Main Street, Wellsville, UT 84339.
Town of Clarkston	Town Hall, 50 South Main Street, Clarkston, UT 84305.
Town of Paradise	Town Hall, 9035 South 100 West, Paradise, UT 84328.
Unincorporated Areas of Cache County	Cache County Public Works Department, 179 North Main Street, Suite 305, Logan, UT 84321.

[FR Doc. 2021–28038 Filed 12–23–21; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2021–0002; Internal Agency Docket No. FEMA–B–2172]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency; Department of Homeland Security.

ACTION: Notice; correction.

SUMMARY: On October 13, 2021, FEMA published in the **Federal Register** a proposed flood hazard determination notice that contained an erroneous table. This notice provides corrections to that table to be used in lieu of the erroneous information. The table provided here represents the proposed flood hazard determinations and communities affected for Prince Edward County, Virginia and Incorporated Areas.

DATES: Comments are to be submitted on or before March 28, 2022.

ADDRESSES: The Preliminary Flood Insurance Rate Map (FIRM), and where applicable, the Flood Insurance Study (FIS) report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–2172, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed in the table below, in accordance with Section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP may only be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a

mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://floodsrp.org/pdfs/srp_fact_sheet.pdf.*

The communities affected by the flood hazard determinations are provided in the table below. Any request for reconsideration of the revised flood hazard determinations shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations will also be considered before the FIRM and FIS report are made final.

Correction

In the proposed flood hazard determination notice published at 86 FR 56972 in the October 13, 2021, issue of the **Federal Register**, FEMA published a table titled Prince Edward County, Virginia and Incorporated Areas. This table contained inaccurate information as to the community map repository for the Unincorporated Areas of Prince Edward County featured in the table. In this document, FEMA is publishing a table containing the accurate information. The information provided below should be used in lieu of that previously published.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Prince Edward County, Virginia and Incorporated Areas Project: 19–03–0018S Preliminary Date: April 14, 2021	
Unincorporated Areas of Prince Edward County	Prince Edward County Administrator's Office, 111 North South Street, Farmville, VA 23901.

[FR Doc. 2021–28036 Filed 12–23–21; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2021–0051]

Identifying Recommendations To Support the Work of the Interagency Task Force on the Reunification of Families; Extension of Comment Period

AGENCY: Department of Homeland Security.

ACTION: Extension of comment period.

SUMMARY: The Department of Homeland Security (DHS), on behalf of the Interagency Task Force on the Reunification of Families (Task Force), is extending the deadline for the submission of public comments in response to its December 10, 2021 request for comments regarding ways to minimize the separation of migrant parents and legal guardians and children entering the United States, consistent with the law.

DATES: The deadline for the request for comments published December 10, 2021, at 86 FR 70512, is extended. Public comments must be submitted no later than January 25, 2022.

ADDRESSES: You may submit comments, identified by docket number DHS–2021–0051, through the Federal eRulemaking Portal: *https://www.regulations.gov.* Comments submitted in any other manner, including emails or letters sent to Task Force officials, may not be reviewed by the Task Force. The Task Force cannot accept any comments that are hand delivered or couriered. In addition, the Task Force cannot accept comments contained on any form of digital media storage devices, such as CDs/DVDs and USB drives. Due to COVID–19, the Task Force is also not accepting mailed comments at this time. If you cannot submit your comment by using *https://www.regulations.gov,* please contact Samantha Deshommes, Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, by telephone at (240) 721–3000 for alternate instructions.

FOR FURTHER INFORMATION CONTACT: Carrie Anderson, Director of Policy for the Family Reunification Task Force, U.S. Department of Homeland Security, (240) 721–3000 (this is not a toll-free number). Individuals with hearing or speech impairments may access the telephone numbers above via TTY by calling the toll-free Federal Information Relay Service at 1–877–889–5627.

SUPPLEMENTARY INFORMATION: December 10, 2021, at 86 FR 70512, DHS, on behalf of the Task Force, published a request for comments regarding ways to minimize the separation of migrant parents and legal guardians and children entering the United States, consistent with the law. The public comment period was initially set to expire at the end of January 10, 2022.

This notice extends the deadline to submit comments to no later than January 25, 2022.

This notice is issued under authority of 5 U.S.C. 552(a).

Michelle Brané,

Executive Director, Interagency Task Force on the Reunification of Families, U.S. Department of Homeland Security.

[FR Doc. 2021–27935 Filed 12–23–21; 8:45 am]

BILLING CODE 9110–9B–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA–2003–14610]

Revision of Agency Information Collection Activity Under OMB Review: Security Threat Assessment for Individuals Applying for a Hazardous Materials Endorsement for a Commercial Driver's License

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-Day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0027, abstracted below to OMB for review and approval of revision of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. The collection involves the submission of biometric and biographic information that TSA uses to verify identity and conduct a security threat assessment (STA) required before

obtaining the hazardous materials endorsement (HME) on a commercial driver's license (CDL) issued by States and the District of Columbia, and a customer satisfaction survey.

DATES: Send your comments by January 26, 2022. A comment to OMB is most effective if OMB receives it within 30 days of publication.

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 find function.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh, TSA PRA Officer, Information Technology (IT), TSA–11, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598–6011; telephone (571) 227–2062; email *TSAPRA@tsa.dhs.gov.*

SUPPLEMENTARY INFORMATION: TSA published a **Federal Register** notice soliciting comments for a 60-day period on April 8, 2021, 86 FR 18293.

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation will be available at *http://www.reginfo.gov* upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Security Threat Assessment for Individuals Applying for a Hazardous Materials Endorsement for a Commercial Driver's License.

Type of Request: Revision of a currently approved collection.

OMB Control Number: 1652–0027.

Forms(s): HME Threat Assessment Program (HTAP) Disclosure and Certification Form, HME Pre-Enrollment Application, HME Enrollment Application, and HME Customer Satisfaction Survey.

Affected Public: Drivers seeking an HME on their state-issued CDL.

Abstract: This collection supports the implementation of sec. 1012 of the USA PATRIOT Act,[1] which mandates that no State or the District of Columbia may issue an HME on a CDL unless TSA has first determined the driver is not a threat to transportation security. TSA's implementing regulations (codified at 49 CFR part 1572) describe the procedures, standards, and eligibility criteria for STAs on individuals seeking to obtain, renew, or transfer an HME on a state-issued CDL. To conduct the STA for the HME, States (or a TSA-designated agent in States that elect to have TSA perform the collection of information) must collect additional information beyond that already collected for the purpose of HME applications (which occur approximately once every five years). The driver is required to submit an application that includes personal information including driver's legal name; current and previous mailing addresses; date of birth; gender; height, weight, eye, and hair color; city, state, and country of birth; social security number (optional); immigration status; mental incapacity; criminal history; and biometrics, such as fingerprints.

States or the TSA agent must also submit whether the driver is a new applicant or applying to renew or transfer the HME. This information is necessary for TSA to forecast driver retention, transfer rate, and drop rate to help improve customer service and reduce program costs. This information also may be necessary to provide comparability with other Federal background checks, including the Transportation Worker Identification Credential.

When the STA is complete, TSA makes a final determination on eligibility for the HME and notifies States of its decision and may provide notifications to the HME applicants of its decision. Most States and applicants will receive notification from TSA within two to three weeks of the submission of their completed applications. If TSA identifies potentially disqualifying information, it will send a letter to the HME applicants with instructions on how to proceed. If initially deemed ineligible by TSA, applicants will have an opportunity to apply for an appeal or waiver. Applicants must submit an application for appeal or waiver within 60 days of issuance of TSA's notification of ineligibility. If an application for appeal or waiver is not received by TSA within the specified amount of time, the agency may make a final determination to deny eligibility.

TSA is revising the collection to reflect three changes to the program: (1) Online renewal capability; (2) enrollment in Rap Back; and (3) expanding enrollment options. First, the implementation of an online renewal capability for both active HME holders whose STA has not yet expired as well as HME holders who have a recently expired STA. Approximately 60 percent of active HME holders enroll to renew their HME when it expires every five years. Online HME renewals will reduce the applicant's cost and hour burden by avoiding visiting a TSA enrollment center for the renewal of a STA.

Second, TSA is revising the collection of biometric fingerprints in States serviced by TSA's enrollment contractor to enroll HME holders in Rap Back, a service provided by the Federal Bureau of Investigation (FBI). Once an individual is enrolled in Rap Back, TSA will not be required to collect new biometric fingerprints from the individual every five years or collect a fee from the individual for the submission of fingerprints to the FBI. The implementation of Rap Back recurrent criminal history vetting for HME holders will mitigate certain security risks posed by individuals who commit a disqualifying offense after their STA is completed and the HME is issued. These changes implementing online renewals and the use of Rap Back will result in lower costs to TSA, which in turn reduces the STA fee applicants must pay.

Third, TSA is revising the collection of information to expand enrollment options and the potential use of biographic and biometric (*e.g.,* fingerprints, iris scans, and/or photo) information. This revision would allow for facilitation of the security threat assessment and future use of the information collected for additional comparability determinations, such as allowing the HME applicant to obtain a Transportation Worker Identification Credential (TWIC®) without requiring an additional background check.

[1] Public Law 107–56 (115 Stat. 272, 396; Oct. 26, 2001) as codified at 49 U.S.C. 5103a.

Finally, TSA invites all HME applicants who enroll using TSA's enrollment provider to complete an optional survey to gather information on the applicant's overall customer satisfaction with the enrollment process. This optional survey is administered at the conclusion of the enrollment process, including the new online renewals, where applicable. The results from these surveys are compiled to produce reports that are reviewed by the enrollment services provider and TSA.

Number of Annual Respondents: 247,952.

Estimated Annual Burden Hours: An estimated 332,978 hours annually.

Estimated Annual Cost: $19.80 million.

Dated: December 21, 2021.

Christina A. Walsh,

TSA Paperwork Reduction Act Officer, Information Technology.

[FR Doc. 2021–28041 Filed 12–23–21; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[222A2100DD/AAKC001030/A0A501010.999900253G]

Indian Gaming; Approval of Tribal-State Class III Gaming Compact in the State of Washington

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice publishes the approval of the Seventh Amendment to the Tribal State Compact (Compact) for Class III Gaming between the Muckleshoot Indian Tribe (Tribe) and the State of Washington (State).

DATES: The Amendment takes effect on December 27, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, *paula.hart@bia.gov,* (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The Compact modifies two existing appendices Appendix A and X2, and adopts three new appendices, Appendix E, T, and W. The Compact is approved.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2021–27976 Filed 12–23–21; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[222D0102DR/DS5A300000/DR.5A311.IA000118]

Resumption of Preparation of an Environmental Impact Statement for the Proposed Coquille Indian Tribe Fee-to-Trust and Gaming Facility Project, Medford, Oregon

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Assistant Secretary—Indian Affairs has withdrawn the Department of the Interior's previous denial of the Coquille Indian Tribe's (Tribe) application to transfer land into trust in Medford, Oregon. Pursuant to this notice, the Bureau of Indian Affairs (BIA) will resume preparation of an environmental impact statement (EIS) for the proposed project.

DATES: On November 19, 2021, the Assistant Secretary—Indian Affairs remanded the Tribe's application to the BIA to complete the environmental review process.

FOR FURTHER INFORMATION CONTACT: Mr. Bryan Mercier, Northwest Regional Director, Bureau of Indian Affairs, Northwest Region, 911 Northeast 11th Avenue, Portland, Oregon 97232–4165.

SUPPLEMENTARY INFORMATION: On January 15, 2015, the BIA published in the **Federal Register** a Notice of Intent to prepare an EIS for the Tribe's application for fee-to-trust acquisition of 2.42 acres and a gaming facility project in Medford, Oregon. The BIA initiated scoping on February 2, 2015. On May 27, 2020, the Principal Deputy Assistant Secretary—Indian Affairs declined to accept conveyance of the Medford Site into trust (2020 Denial). On November 19, 2021, the Assistant Secretary—Indian Affairs withdrew the 2020 Denial and remanded the Tribe's application to the BIA to complete the environmental review process under the National Environmental Policy Act (NEPA). Pursuant to this Notice, the BIA will resume preparation of the EIS. The EIS is being prepared for the Tribe's application requesting that the United States acquire in trust approximately 2.42 acres of land within the City of Medford, Jackson County, Oregon. The Tribe is proposing to retrofit and remodel an existing bowling alley into a 30,300-square-foot gaming facility.

Authority: This notice is published in accordance with sections 1501.7 and 1506.6 of the Council on Environmental Quality Regulations (40 CFR parts 1500 through 1508) implementing the procedural requirements of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321–4345 *et seq.*), and the Department of the Interior National Environmental Policy Act Regulations (43 CFR part 46), and is in the exercise of authority delegated to the Assistant Secretary—Indian Affairs by 209 DM 8.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2021–27953 Filed 12–23–21; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[222A2100DD/AAKC001030/A0A501010.999900253G]

Indian Gaming; Approval of Tribal-State Class III Gaming Compact in the State of Washington

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice publishes the approval of the Memorandum of Incorporation of Most Favored Nation Amendments to the Tribal State Compact (Amendment) between the Lummi Nation (Nation) and the State of Washington (State).

DATES: The Amendment takes effect on December 27, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, *paula.hart@bia.gov,* (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The Amendment updates the gambling age limit at the Tribe's class III

gaming facilities. The Amendment is approved.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2021–27975 Filed 12–23–21; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Office of Natural Resources Revenue

[Docket No. ONRR–2011–0002; DS63644000 DRT000000.CH7000 223D1113RT]

States' Decisions on Participating in Accounting and Auditing Relief for Federal Oil and Gas Marginal Properties

AGENCY: Office of Natural Resources Revenue, Interior.

ACTION: Notice.

SUMMARY: In accordance with Office of Natural Resources Revenue (ONRR) regulations, ONRR provides two types of accounting and auditing relief for Federal oil and gas production from marginal properties: (1) The cumulative royalty reports and payments relief option, which allows a lessee or designee to submit one royalty report and payment for the calendar year's production; and (2) other requested relief, which allows a lessee or designee to request any type of accounting and auditing relief that is appropriate for production from the marginal property and meets certain requirements. By October 1 of each calendar year, ONRR provides a list of qualifying marginal Federal oil and gas properties to the States receiving a portion of Federal royalties from those properties. Each State then decides whether to participate in neither, one, or both relief options. This Notice provides the public each State's decision on whether to participate in marginal property relief.

DATES: Effective January 1, 2022.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Sudar, Market and Spatial Analytics, Coordination, Enforcement, Valuations, and Appeals Division, ONRR, at (303) 231–3511; or by email to *Robert.Sudar@onrr.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Oil and Gas Royalty Simplification and Fairness Act of 1996 (30 U.S.C. 1726) and 30 CFR part 1204, subpart C, ONRR and States can relieve the lessee of a marginal Federal oil and gas property from certain reporting, accounting, and auditing requirements. ONRR's rules under 30 CFR 1204.202 and 1204.203 authorize two relief options: (1) Cumulative royalty reports and payments relief option, which allows a lessee or designee to submit one royalty report and payment during a calendar year; and (2) other requested relief, which allows a lessee or designee to request any type of appropriate marginal property accounting and auditing relief that meets the requirements under § 1204.5 and is not prohibited under § 1204.204.

To qualify for the first relief option, *cumulative royalty reports and payments relief option,* properties must produce less than 1,000 barrels-of-oil-equivalent (BOE) per year for the base period (July 1, 2020 through June 30, 2021). Annual reporting relief will begin January 1, 2022, with the annual report and payment due February 28, 2023. If a lessee has an estimated payment on file, the payment due date is March 31, 2023. To qualify for the second relief option, *other requested relief,* the combined equivalent production of the marginal properties during the base period must equal an average daily well production of less than 15 BOE per well per day, as calculated under 30 CFR 1204.4(c).

Each State makes an annual determination as to whether it will participate in neither, one, or both relief options. This Notice fulfills the requirement in ONRR's rules to publish a notice of the State's ''intent to allow or not allow certain relief options . . . in the Federal Register no later than 30 days before the beginning of the applicable calendar year.'' *See* 30 CFR 1204.208(f).

The following table shows the States with qualifying marginal properties and those States' decisions on whether to participate in neither, one, or both relief options for calendar year 2022. An ''N/A'' means that no properties within the State met that condition for that type of relief:

State	Cumulative royalty report and payment relief (less than 1,000 BOE per year)	Other accounting and auditing relief (less than 15 BOE per well per day)
Alabama	YES	YES.
Arkansas	N/A	YES.
California	NO	NO.
Colorado	NO	NO.
Kansas	NO	NO.
Louisiana	YES	YES.
Michigan	YES	YES.
Montana	NO	NO.
Nebraska	N/A	NO.
Nevada	YES	YES.
New Mexico	NO	YES.
North Dakota	YES	YES.
Oklahoma	NO	NO.
South Dakota	YES	YES.
Utah	NO	NO.
Wyoming	YES	NO.

Pursuant to 30 U.S.C. 1726(c), a Federal oil and gas property located in a State where ONRR does not share a portion of Federal royalties with that State (that is, for 2022, a State not listed in the table above) is eligible for relief if it qualifies as a marginal property. For more information on how to obtain relief, please refer to 30 CFR 1204.205.

Unless the information that ONRR receives is proprietary data, all correspondence, records, or information received in response to this notice may be subject to disclosure under the Freedom of Information Act (FOIA, 5 U.S.C. 552 *et seq.*). If applicable, please highlight the proprietary portions, including any supporting documentation, or mark the page(s) containing proprietary data. ONRR protects proprietary information under the Trade Secrets Act (18 U.S.C. 1905), FOIA Exemption 4 (5 U.S.C. 552(b)(4)), and the Department of the Interior's FOIA regulations (43 CFR part 2).

Authority: Federal Oil and Gas Royalty Management Act of 1982, 30 U.S.C. 1701 *et seq.,* as amended by Federal Oil and Gas Royalty Simplification and Fairness Act of 1996 (RSFA, Pub. L. 104–185—Aug. 13, 1996, as corrected by Pub. L. 104–200—Sept. 22, 1996).

Kimbra G. Davis,

Director, Office of Natural Resources Revenue.

[FR Doc. 2021–28045 Filed 12–23–21; 8:45 am]

BILLING CODE 4335–30–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–972 (Rescission)]

Certain Automated Teller Machines, ATM Modules, Components Thereof, and Products Containing the Same; Commission Decision To Institute a Rescission Proceeding; Rescission of a Limited Exclusion Order and Cease and Desist Orders; Termination of Rescission Proceeding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined to institute a rescission proceeding in the above-captioned investigation and to grant a joint motion for rescission of a limited exclusion order (''LEO'') and three cease and desist orders (''CDOs'') previously issued in the investigation. The LEO and CDOs are rescinded, and the rescission proceeding is terminated.

FOR FURTHER INFORMATION CONTACT: Sidney A. Rosenzweig, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–2532. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (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 *https://www.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 instituted this investigation on November 20, 2015, based on a complaint filed by Diebold Incorporated and Diebold Self-Service Systems (collectively, ''Diebold''). 80 FR 72735–36 (Nov. 20, 2015). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 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 automated teller machines, ATM modules, components thereof, and products containing the same by reason of infringement of certain claims of six United States Patents, including U.S. Patent No. 6,082,616 (''the '616 patent''); and U.S. Patent No. 7,832,631 (''the '631 patent''). *Id.* The notice of investigation named as respondents Nautilus Hyosung Inc. of Seoul, Republic of Korea; Nautilus Hyosung America Inc. of Irving, Texas (collectively, ''Nautilus''); and HS Global, Inc. of Brea, California (''HS Global''). *Id.* at 72736. The Office of Unfair Import Investigations was not named as a party. *Id.* Nautilus Hyosung Inc. subsequently changed its name to Hyosung TNS Inc. *See* Commission Order Amending the Remedial Orders at 1 n.1 (Aug. 13, 2019).

On May 19, 2017, the Commission terminated the investigation with a finding of violation of section 337 as to certain claims of the '616 patent and '631 patent. 82 FR 24143–44 (May 25, 2017). The Commission issued a limited exclusion order prohibiting the entry of infringing automated teller machines, ATM modules, components thereof, and products containing the same, and (2) cease and desist orders directed to each of the three respondents. *Id.* at 24144. On August 13, 2019, the Commission amended the remedial orders to remove the references to the '616 patent, which had expired on June 2, 2018. Order at 2 (Aug. 13, 2019); *see generally Hyosung TNS Inc.* v. *ITC,* 926 F.3d 1353, 1359 (Fed. Cir. 2019) (finding any disputes concerning the '616 patent to have been mooted by that patent's expiration).

On December 1, 2021, Diebold and Nautilus jointly filed confidential and public versions of a petition to rescind all of the remedial orders based on a settlement agreement. No responses to the petition were filed. Despite that HS Global is not a party to the settlement, Diebold and Nautilus seek the rescission of the remedial orders in their entirety. Diebold and Nautilus also moved that service among the private parties of the settlement agreement be limited to Diebold and Hyosung, and not to HS Global. The Commission has determined to grant that request concerning service.

Having reviewed the petition and determined that it complies with Commission rules, *see* 19 CFR 210.76(a)(3), the Commission has determined to institute a rescission proceeding and to grant the petition. The LEO and the CDOs directed to each of the three respondents are hereby rescinded.

The rescission proceeding is terminated.

The Commission vote for this determination took place on December 20, 2021.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: December 21, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–28015 Filed 12–23–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1275]

Certain Networking Devices, Computers, and Components Thereof ; Notice of a Commission Determination Not To Review an Initial Determination Terminating the Investigation on the Basis of Settlement; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 11) terminating the investigation on the basis of settlement. The investigation is terminated in its entirety.

FOR FURTHER INFORMATION CONTACT: Amanda P. Fisherow, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2737. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket 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 *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted the present investigation on August 13, 2021, based on a complaint and supplement thereto filed by Proven Networks, LLC of Los Angeles, California (''Complainant''). 86 FR 44746–47 (Aug. 13, 2021). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation, sale for importation, and sale in the United States after importation of certain networking devices, computers, and components thereof that allegedly infringe certain claims of U.S. Patent No. 8,687,573. *Id.* The complaint further alleged that an industry in the United States exists, or is in the process of being established, as required by section 337. *Id.* The notice of investigation named F5 Networks Inc. of Seattle, Washington as the respondent. *Id.* at 44747. The Office of Unfair Import Investigations was also named as a party to this investigation. *Id.*

On December 2, 2021, the private parties filed a joint unopposed motion to terminate the investigation on the basis of settlement. The parties represented that ''there are no other agreements, written or oral, express or implied, between the Parties regarding the subject matter of this proceeding.''

On December 3, 2021, the presiding administrative law judge issued Order No. 11, granting the joint motion to terminate the investigation on the basis of settlement. The ID found that the motion complies with the requirements

of Commission Rule 210.21 (19 CFR 210.21(a), (b)) and that there is no evidence that indicates that termination would adversely affect the public interest. No party filed a petition for review of the ID.

The Commission has determined not to review this ID. Accordingly, the investigation is terminated.

The Commission vote for this determination took place on December 20, 2021.

The authority for the Commission's determination is contained in Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: December 20, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–27943 Filed 12–23–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1224]

Certain Digital Video-Capable Devices and Components Thereof; Commission Determination To Review a Final Initial Determination Finding No Violation of Section 337; Request for Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding; Extension of the Target Date

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined to review a final initial determination (''ID'') of the presiding administrative law judge (''ALJ''). The Commission requests written submissions from the parties on the issues under review and submissions from the parties, interested government agencies, and other interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below. The Commission also extends the target date for completion of the investigation until March 23, 2022.

FOR FURTHER INFORMATION CONTACT: Amanda P. Fisherow, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2737. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (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 *https://www.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 instituted the present investigation on October 22, 2020, based on a complaint and supplement thereto filed by Koninklijke Philips N.V. of Eindhoven, Netherlands and Philips North America LLC of Cambridge, Massachusetts (collectively, ''Philips''). 85 FR 67373–74 (Oct. 22, 2020). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation, sale for importation, and sale in the United States after importation of certain digital video-capable devices and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 9,436,809 (''the '809 patent''); 9,590,977 (''the '977 patent''); 10,091,186 (''the '186 patent''); and 10,298,564 (''the '564 patent''). *Id.* at 67373. The complaint further alleged that an industry in the United States exists or is in the process of being established, as required by section 337. *Id.* The notice of investigation named the following respondents: Dell Technologies Inc. of Round Rock, Texas and Dell Inc. of Round Rock, Texas (together ''Dell''); Hisense Co. Ltd. of Qingdao, China, Hisense Visual Technology Co., Ltd. of Qingdao, China, Hisense Electronics Manufacturing Company of America Corporation of Suwanee, Georgia, Hisense USA Corporation of Suwanee, Georgia, Hisense Import & Export Co. Ltd. of Qingdao, China, Hisense International Co., Ltd. of Qingdao, China, Hisense International (HK) Co., Ltd. of Sheung Wan, Hong Kong (SAR), and Hisense International (Hong Kong) America Investment Co., Ltd. of Sheung Wan, Hong Kong (SAR) (together, ''Hisense''); HP, Inc. of Palo Alto, California (''HP''); Lenovo Group Ltd. of Quarry Bay, Hong Kong (SAR) and Lenovo (United States), Inc. of Morrisville, North Carolina (together, ''Lenovo''); LG Electronics, Inc. of Seoul, Republic of Korea and LG Electronics USA, Inc. of Englewood Cliffs, New Jersey; TCL Industries Holdings Co., Ltd., of Guangdong, China, TCL Electronics Holdings Ltd. of Hong Kong Science Park, Hong Kong (SAR), TCL King Electrical Appliances (Huizhou) Co. Ltd. of Huizhou, China, TTE Technology, Inc. of Corona, California, TCL Moka International Ltd. of Sha Tin, Hong Kong, TCL Moka Manufacturing S.A. de C.V. of Tijuana, Mexico, TCL Smart Device (Vietnam) Company Ltd. of Binh Duong, Vietnam; MediaTek Inc. of Hsinchu, Taiwan and MediaTek USA Inc. of San Jose, California; Realtek Semiconductor Corp. of Hsinchu, Tiawan (''Realtek''); and Intel Corporation of Santa Clara, California (''Intel''). *Id.* at 67374. The Office of Unfair Import Investigations (''OUII'') is participating in the investigation. *Id.*

During the course of the investigation, Philips moved to terminate the investigation as to various claims, patents, and respondents. *See* Order No. 19, *unreviewed by* Comm'n Notice (Apr. 15, 2021), Order No. 21, *unreviewed by* Comm'n Notice (May 12, 2021), Order No. 26, *unreviewed by* Comm'n Notice (Jun 21, 2021), Order 32, *unreviewed by* Comm'n Notice (July 26, 2021), Order No. 40, *unreviewed by* Comm'n Notice (Aug. 2, 2021), and Order No. 46, *unreviewed by* Comm'n Notice (Aug. 10, 2021). The Respondents remaining in the investigation are Dell, Hisense, HP, Lenovo, TCL, Realtek, and Intel (together, ''the Respondents''). The remaining asserted patent claims are: claims 1, 9, 11, 12, and 14 of the '186 patent; and claims 1, 18, 19, 21, and 25 of the '564 patent.

On October 21, 2021, the ALJ issued the subject ID. On November 2, 2021, Philips and OUII each filed petitions for review. Also, on November 2, 2021, Respondents Intel, Dell, and Lenovo filed a contingent petition for review and Respondents HP, Realtek, Dell, Lenovo, Hisense, and TCL (''Receiver Respondents'') filed a separate contingent petition for review. On November 10, 2021, Philips, OUII, and the Respondents each filed replies.

Having reviewed the record of the investigation, including the final ID, the parties' submissions to the ALJ, and the petitions for review and replies, the Commission has determined to review the ID in part. Specifically, the Commission has determined to review the ID's findings on claim construction, infringement, validity, and domestic industry for both of the '186 and '564 patents.

In connection with its review, the Commission requests responses to the following questions. The parties are requested to brief their positions with reference to the applicable law and the existing evidentiary record.

(1) Please discuss whether the evidence establishes that the claimed ''certificate'' of the accused products and domestic industry products indicates that the second device is compliant with at least one compliance rule. In your discussion, please address the specific compliance rule(s) at issue and specifically how the certificate indicates that the second device is compliant with the compliance rule(s). Please address the evidence in the contexts of both the '186 and '564 patents.

(2) Does any of the information contained within the alleged ''certificate'' of the accused products or domestic industry products [[ ]]? *See, e.g.,* ID at 73–75.

(3) Should ''when,'' as recited in the asserted claims, be interpreted to mean ''when and only when''? *See* Complainants' Petition for Review at 23. Did Complainants waive their argument that the accused products infringe if ''when'' is construed to mean ''when and only when''? Please address the intrinsic record in your response and any relevant Federal Circuit case law.

(4) Discuss the capabilities of the accused receiver products (and the domestic industry products, if relevant) and whether they have instructions arranged to receive protected content only when the claimed conditions are satisfied (*i.e.,* [[ ]]).

(5) Please address whether the ''predetermined time'' limitations of the asserted claims are met if ''predetermined time'' is construed as ''a time interval selected to ensure that the first and second communication devices are sufficiently near one another to permit access to the protected content.'' *See, e.g.,* Receiver Respondents Petition for Review at 18. Please address this question both for infringement and the technical prong of domestic industry.

(6) Please discuss whether the Commission should apply the America Invents Act (''AIA'') or pre-AIA statute in evaluating Respondents' validity challenges and in determining the proper priority date.

(7) If the Commission determines that the ID, in addressing domestic industry, properly considered labor investments only for 2020 (*see* ID at 143–149):

a. What is the proper allocation percentage that should be applied? Please support your argument with citations to record evidence.

b. Can data on one year of investments support the significance of an industry that is already established? Please support your argument with reference to the statute and any relevant Commission and judicial precedent.

The parties are invited to brief only the discrete issues requested above. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia,* (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843, Comm'n Op. at 7–10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and cease and desist orders would have on: (1) The public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy, the public interest, and bonding.

In its initial submission, Complainant is also requested to identify the remedy sought and Complainant and OUII are requested to submit proposed remedial orders for the Commission's consideration. Complainant is further requested to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than close of business on January 7, 2022. Reply submissions must be filed no later than the close of business on January 14, 2022. Opening submissions are limited to 60 pages. Reply submissions are limited to 35 pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (Inv. No. 337–TA–1224) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205–2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. 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, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission extends the target date for completion of the investigation to March 23, 2022.

The Commission vote for this determination took place on December 20, 2021.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: December 20, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–27945 Filed 12–23–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1288]

Certain Playards and Strollers; Notice of Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on November 24, 2021, under section 337 of the Tariff Act of 1930, as amended, on behalf of Graco Children's Products Inc. of Atlanta, Georgia and Wonderland Nurserygoods Co., Ltd. of Taiwan. A supplement to the complaint was filed on December 13, 2021. The complaint, as supplemented, 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 playards and strollers by reason of infringement of certain claims of U.S. Patent No. 9,706,855 (''the '855 patent''); U.S. Patent No. 9,414,694 (''the '694 patent''); U.S. Patent No. RE43,919 (''the '919 patent'') and U.S. Patent No. 6,979,017 (''the '017 patent''). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute. The complainants request 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 advised that 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: Jessica Mullan, 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 (2020).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on December 20, 2021, *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 1–20 of the '855 patent; claims 1, 2, 4–20 of the '694 patent; claims 8, 10–12, 14–20, 27, and 28 of the '919 patent; and claims 1–6 of the '017 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 ''foldable child containment systems, generally known as playards, including those with a bassinet and/or an infant support unit in different configurations; and foldable strollers'';

(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: Graco Children's Products Inc., 6655 Peachtree Dunwoody Road, Atlanta, GA 30328.

Wonderland Nurserygoods Co., Ltd., Rui Kwang Road, No. 433, 10th Floor, Neihu, Taipei, Taiwan 114691.

(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: Baby Trend, Inc., 13048 Valley Blvd., Fontana, CA 92335.

Dongguan Golden Prosper Baby Products Co., Ltd., Unit 1, No. 10 Lengshuikeng Road, Huang Feng Ling Industrial Park, Luo Ma Village, Qing Xi Town, Dongguan City, Guangdong, China, 523660.

Sichuan Hobbies Baby Products Co., Ltd., Sandaoqiao Industrial Park, Longchang City, Neijiang, Sichuan, China, 642150.

Anhui Chile Baby Products Co., Ltd., No. 1, 9th Road, Feidong Xincheng Develop Zone, Anhui Province, China, 231600.

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations is not participating as a party in this investigation.

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 complainants 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: December 20, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–27941 Filed 12–23–21; 8:45 am]

BILLING CODE 7020–02–P

JUDICIAL CONFERENCE OF THE UNITED STATES

Committee on Rules of Practice and Procedure; Meeting of the Judicial Conference

AGENCY: Judicial Conference of the United States.

ACTION: Committee on Rules of Practice and Procedure; revised notice of open meeting.

SUMMARY: The Committee on Rules of Practice and Procedure will hold a virtual meeting on January 4, 2022 rather than in Washington, DC as previously announced. The meeting is open to the public for observation but not participation. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: *http://www.uscourts.gov/rules-policies/records-and-archives-rules-committees/agenda-books.* The announcement for this meeting was previously published in the **Federal Register** on October 26, 2021.

DATES: January 4, 2022.

FOR FURTHER INFORMATION CONTACT: Bridget Healy, Esq., Acting Chief Counsel, Rules Committee Staff, Administrative Office of the U.S. Courts, Thurgood Marshall Federal Judiciary Building, One Columbus Circle NE, Suite 7–300, Washington, DC 20544, Phone (202) 502–1820, *RulesCommittee_Secretary@ao.uscourts.gov.*

(Authority: 28 U.S.C. 2073.)

Dated: December 21, 2021.

Shelly L. Cox,

Management Analyst, Rules Committee Staff.

[FR Doc. 2021–27987 Filed 12–23–21; 8:45 am]

BILLING CODE 2210–55–P

JUDICIAL CONFERENCE OF THE UNITED STATES

Advisory Committee on Bankruptcy Rules; Meeting of the Judicial Conference

AGENCY: Judicial Conference of the United States.

ACTION: Advisory Committee on Bankruptcy Rules; notice of open meeting.

SUMMARY: The Advisory Committee on Bankruptcy Rules will hold a meeting on March 31, 2022 in San Diego, CA. The meeting is open to the public for observation but not participation. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: *http://www.uscourts.gov/rules-policies/records-and-archives-rules-committees/agenda-books.*

DATES: March 31, 2022.

FOR FURTHER INFORMATION CONTACT: Bridget Healy, Esq., Acting Chief Counsel, Rules Committee Staff, Administrative Office of the U.S. Courts, Thurgood Marshall Federal Judiciary Building, One Columbus Circle NE, Suite 7–300, Washington, DC 20544, Phone (202) 502–1820, *RulesCommittee_Secretary@ao.uscourts.gov.*

(Authority: 28 U.S.C. 2073.)

Dated: December 21, 2021.

Shelly L. Cox,

Management Analyst, Rules Committee Staff.

[FR Doc. 2021–27986 Filed 12–23–21; 8:45 am]

BILLING CODE 2210–55–P

JUDICIAL CONFERENCE OF THE UNITED STATES

Advisory Committee on Appellate Rules; Meeting of the Judicial Conference

AGENCY: Judicial Conference of the United States.

ACTION: Advisory Committee on Appellate Rules; notice of open meeting.

SUMMARY: The Advisory Committee on Appellate Rules will hold a meeting on March 30, 2022 in San Diego, CA. The meeting is open to the public for observation but not participation. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: *http://www.uscourts.gov/rules-policies/records-and-archives-rules-committees/agenda-books.*

DATES: March 30, 2022.

FOR FURTHER INFORMATION CONTACT: Bridget Healy, Esq., Acting Chief Counsel, Rules Committee Staff, Administrative Office of the U.S. Courts, Thurgood Marshall Federal Judiciary Building, One Columbus Circle NE, Suite 7–300, Washington, DC 20544, Phone (202) 502–1820, *RulesCommittee_Secretary@ao.uscourts.gov.*

(Authority: 28 U.S.C. 2073.)

Dated: December 21, 2021.

Shelly L. Cox,

Management Analyst, Rules Committee Staff.

[FR Doc. 2021–27984 Filed 12–23–21; 8:45 am]

BILLING CODE 2210–55–P

JUDICIAL CONFERENCE OF THE UNITED STATES

Advisory Committee on Civil Rules; Meeting of the Judicial Conference

AGENCY: Judicial Conference of the United States.

ACTION: Advisory Committee on Civil Rules; notice of open meeting.

SUMMARY: The Advisory Committee on Civil Rules will hold a meeting on March 29, 2022 in San Diego, CA. The meeting is open to the public for observation but not participation. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: *http://www.uscourts.gov/rules-policies/records-and-archives-rules-committees/agenda-books.*

DATES: March 29, 2022.

FOR FURTHER INFORMATION CONTACT: Bridget Healy, Esq., Acting Chief Counsel, Rules Committee Staff, Administrative Office of the U.S. Courts, Thurgood Marshall Federal Judiciary Building, One Columbus Circle NE, Suite 7–300, Washington, DC 20544, Phone (202) 502–1820, *RulesCommittee_Secretary@ao.uscourts.gov.*

(Authority: 28 U.S.C. 2073.)

Dated: December 21, 2021.

Shelly L. Cox,

Management Analyst, Rules Committee Staff.

[FR Doc. 2021–27985 Filed 12–23–21; 8:45 am]

BILLING CODE 2210–55–P

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. B.S.A. S.A., LAG Holding, Inc., and The Kraft Heinz Company; Complaint, Proposed Final Judgment, and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a Complaint, a proposed Final Judgment, an Asset Preservation and Hold Separate Stipulation and Order, and a Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in *United States of America* v. *B.S.A. S.A., LAG Holding, Inc., and The*

Kraft Heinz Company, Civil Action No. 1:21–cv–02976–RBW. On November 10, 2021, the United States filed a Complaint alleging that B.S.A. S.A.'s proposed acquisition of The Kraft Heinz Company's natural cheese business would violate Section 7 of the Clayton Act, 15 U.S.C. 18. The proposed Final Judgment, filed at the same time as the Complaint, requires B.S.A. S.A. to divest The Kraft Heinz Company's Athenos business—including the worldwide rights to the Athenos brand, under which The Kraft Heinz Company sells feta cheese and other products—to Emmi Roth USA, Inc. or an alternative acquirer approved by the United States. The proposed Final Judgment also requires B.S.A. S.A. to divest The Kraft Heinz Company's Polly-O business—including the worldwide rights to the Polly-O brand, under which The Kraft Heinz Company sells ricotta and other cheeses—to BelGioioso Cheese Inc. or an alternative acquirer approved by the United States.

Copies of the Complaint, proposed Final Judgment, Asset Preservation and Hold Separate Stipulation and Order, and Competitive Impact Statement are available for inspection on the Antitrust Division's website at *https://www.justice.gov/atr/case/us-v-lactalis-et-al* and at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, including the name of the submitter, and responses thereto, will be posted on the Antitrust Division's website, filed with the Court, and, under certain circumstances, published in the **Federal Register**. Comments should be submitted in English and directed to Eric D. Welsh, Chief, Healthcare and Consumer Products Section, Antitrust Division, Department of Justice, 450 Fifth Street NW, Suite 4100, Washington, DC 20530 (email address: *Eric.Welsh@usdoj.gov*).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

United States District Court for the District of Columbia

United States of America, United States Department of Justice, Antitrust Division, 450 Fifth Street NW, Suite 4100, Washington, DC 20530, Plaintiff, v. *B.S.A. S.A., 33 Avenue du Maine, Paris, France 75015, LAG Holding, Inc., 2376 South Park Avenue, Buffalo, NY 14220,* and *The Kraft Heinz Company, One PPG Plaza, Pittsburgh, PA 15222,* Defendants.

Civil Action No.:

Complaint

The United States of America brings this civil antitrust action to enjoin B.S.A. S.A. and its subsidiary, LAG Holding, Inc. (together ''Lactalis''), from acquiring the natural cheese business of The Kraft Heinz Company (''Kraft Heinz'') in the United States. This combination would bring together the two largest suppliers of feta cheese in the United States and the two largest suppliers of ricotta cheese in the metropolitan and surrounding area of New York, New York, and in four metropolitan and surrounding areas in Florida. As a result, the proposed combination of Lactalis and Kraft Heinz would likely lead to higher prices, lower quality, and reduced choice for retail consumers of these cheeses, at a time when many Americans are struggling to meet rising food prices. The transaction should be enjoined to prevent American consumers from suffering these likely anticompetitive harms. The United States alleges as follows:

I. Nature of the Action

1. Grocery and supermarket purchases account for a significant portion of the household budget for American families, and Americans' food bills are rising. According to the USDA's Economic Research Service, grocery prices have increased in 2021, and are expected to further increase in 2022, putting more pressure on American consumers who are struggling to make ends meet. Competition plays an important role in keeping down the prices for grocery items, such as cheese, that Americans purchase and use every day.

2. B.S.A. S.A. is one of the world's largest dairy companies, manufacturing and selling cheese in the United States through its subsidiaries, LAG Holding, Inc. and Lactalis American Group, Inc. In the United States, Lactalis sells natural cheeses primarily under the Galbani and Président brand names. Kraft Heinz is one of the largest food products and beverage companies in the world. Kraft Heinz is also the largest supplier of natural cheeses to grocery stores and other retail outlets in the United States, selling natural cheeses primarily under the Kraft, Cracker Barrel, Athenos, and Polly-O brand names.

3. On September 15, 2020, B.S.A. S.A. agreed to pay approximately $3.2 billion to acquire Kraft Heinz's (1) natural cheese business in the United States, which includes feta, ricotta, and many other types of cheeses, but excludes processed cheese and cream cheese, (2) grated cheese business in Canada, and (3) entire cheese business outside North America (the ''proposed transaction'').

4. The proposed transaction would combine the two largest suppliers of feta cheese sold to retailers in the United States, and the two largest suppliers of ricotta cheese sold to retailers in five metropolitan and surrounding areas located in New York and Florida. If allowed to proceed, the merged firm's brands would control approximately 65% of all retail feta sales (brands and private label) nationwide, with its next closest branded competitor controlling approximately 6% of retail feta sales. For ricotta, the merged firm's brands would control approximately 70% of all retail sales (brands and private label) in the metropolitan and surrounding area of New York, New York, with its next closest branded competitor controlling approximately 7% of retail ricotta sales in that market. And in each of the four metropolitan and surrounding areas in Florida identified below, the merged firm's brands would control over 65% of all retail ricotta sales (brands and private label), with its next closest branded competitor in each of the markets controlling no more than 2% of retail ricotta sales.

5. Defendants are particularly close competitors for the sale of feta (through Lactalis's Président brand and Kraft Heinz's Athenos brand) and ricotta (through Lactalis's Galbani brand and Kraft Heinz's Polly-O brand) to retailers. These strong brands allow Lactalis and Kraft Heinz to compete aggressively with each other in the sale of feta and ricotta cheese in the relevant markets, which has resulted in lower prices and innovative products, such as Lactalis's double cream ricotta cheese and Kraft Heinz's flip top container for Athenos crumbled feta cheese, that benefit consumers.

6. The proposed transaction would eliminate this competition, likely leading to higher prices, reduced innovation, and fewer choices for these products for retailers in the relevant markets. For these reasons, the proposed transaction is likely to substantially lessen competition in the sale of feta and ricotta cheeses in the relevant markets, in violation of Section 7 of the Clayton Act, 15 U.S.C. 18. The Court should, therefore, enjoin the proposed transaction.

II. Jurisdiction and Venue

7. The United States brings this action pursuant to Section 15 of the Clayton Act, as amended, 15 U.S.C. 25, to prevent and restrain Defendants from violating Section 7 of the Clayton Act, as amended, 15 U.S.C. 18.

8. Defendants sell cheeses, including feta and ricotta, in the flow of interstate commerce, and their sale of these products substantially affects interstate commerce, including in this judicial district. This Court therefore has subject matter jurisdiction over this action pursuant to Section 15 of the Clayton Act, 15 U.S.C. 25, and 28 U.S.C. 1331, 1337(a), and 1345.

9. Defendants have each consented to personal jurisdiction and venue in this judicial district for purposes of this action. Venue is therefore proper in this district under 28 U.S.C. 1391(b) and (c).

III. The Defendants

10. B.S.A. S.A. is a French company operating under the name Lactalis Group. B.S.A. S.A. is a corporation organized and existing under the laws of France, with its headquarters in Laval, France. It is one of the largest dairy companies in the world.

11. LAG Holding, Inc. is a subsidiary of B.S.A. S.A. It is a Delaware corporation with its headquarters in Buffalo, New York. LAG Holding, Inc. and its subsidiary, Lactalis American Group, Inc., generated natural cheese sales of approximately $429 million at retail outlets in the United States in 2020.

12. Kraft Heinz is a Delaware corporation co-headquartered in Pittsburgh, Pennsylvania, and Chicago, Illinois. Kraft Heinz is one of the largest food products and beverage companies in the world. Retail sales of its natural cheeses in the United States amounted to over $2.2 billion in 2020.

IV. Relevant Markets

13. A typical starting point for merger analysis is defining a relevant market, which has both a product and a geographic dimension. Courts define relevant markets to help determine the areas of competition most likely to be affected by a merger. As described below, both feta cheese sold to retailers across the United States and ricotta cheese sold to retailers in the metropolitan and surrounding area of New York, New York (the ''New York Metro Market'') and in four metropolitan and surrounding areas in Florida—Miami/Ft. Lauderdale, Tampa/St. Petersburg, Orlando, and Jacksonville (collectively, the ''Florida Metro Markets'')—are relevant markets.

A. Relevant Product Markets

14. Cheeses are sold to retailers as branded cheeses or private label cheeses. A branded cheese bears a brand name controlled by the cheese supplier (*e.g.,* Kraft Heinz's Athenos and Polly-O brands and Lactalis's Président and Galbani brands). A branded cheese is usually carried by multiple retailers. A private label cheese is usually sold under a name owned by the retailer (*e.g.,* Wal-Mart's Great Value private label), and is typically offered only in that retailer's stores.

15. Grocery stores and other food retailers act as proxies for individual consumers and seek to offer the variety of products demanded by their customers. As a result, retailers strive to carry products and brands that their customers value, and may vary their offerings to meet local customer demand. For example, Polly-O was founded over 100 years ago in the New York City area, where it became quite popular. As residents of the New York City area visited or moved to Florida, they took their Polly-O brand loyalty with them. Thus, Polly-O ricotta cheese has greater competitive significance in grocery stores and other retailers in the New York Metro Market and the Florida Metro Markets than in other areas of the country.

1. Ricotta Cheese Sold to Retailers Is a Relevant Product Market

16. Ricotta is a soft cheese that originated in Italy. It is primarily used as an ingredient in food dishes.

17. There are no reasonable substitutes for ricotta cheese for most consumers. A hypothetical monopolist supplier of ricotta cheese to retailers likely would find it profitable to increase its prices by at least a small but significant non-transitory amount. Consumers are unlikely to sufficiently reduce their purchases of ricotta cheese or shift to a different cheese or other products to render such a price increase unprofitable. As a result, retailers, buying on behalf of the consumer, are also unlikely to sufficiently reduce purchases of ricotta cheese to render such a price increase unprofitable. Accordingly, ricotta cheese sold to retailers is a relevant product market and line of commerce within the meaning of Section 7 of the Clayton Act.

18. Defining a market for ricotta cheese that is sold to retailers is consistent with industry recognition and practice. Suppliers of ricotta cheese to retailers typically (1) monitor the retail prices of competing ricotta cheeses and set their prices and promotional spending accordingly, (2) do not set the price they charge for ricotta cheese based on the prices of other cheeses or other consumer products, (3) track their sales to retailers separately from their sales to other distribution channels (*i.e.,* foodservice and the ingredients or industrial channels), (4) have sales employees dedicated to serving retailers, and (5) sell ricotta cheese to retailers in packaging and package sizes that are different than that used for ricotta sold through other distribution channels. These factors further support that ricotta cheese sold to retailers is a relevant product market and line of commerce within the meaning of Section 7 of the Clayton Act.

2. Feta Cheese Sold to Retailers Is a Relevant Product Market

19. Feta cheese originated in Greece. It is primarily used as an ingredient in food dishes.

20. There are no reasonable substitutes for feta cheese for most consumers. A hypothetical monopolist supplier of feta cheese to retailers likely would find it profitable to increase its prices by at least a small but significant non-transitory amount. Consumers are unlikely to sufficiently reduce their purchases of feta cheese or shift to a different cheese or other products to render such a price increase unprofitable. As a result, retailers, buying on behalf of the consumer, are also unlikely to sufficiently reduce purchases of feta cheese to render such a price increase unprofitable. Accordingly, feta cheese sold to retailers is a relevant product market and line of commerce within the meaning of Section 7 of the Clayton Act.

21. Defining a market for feta cheese that is sold to retailers is consistent with industry recognition and practice. Suppliers of feta cheese to retailers typically (1) monitor the retail prices of competing feta cheeses and set their prices and promotional spending accordingly, (2) do not set the price they charge for feta based on the prices of other cheeses or other consumer products, (3) track their sales to retailers separately from their sales to other distribution channels, (4) have sales employees dedicated to serving retailers, and (5) sell feta cheese to retailers in packaging and package sizes that are different than that used for feta sold through other distribution channels. These factors further support that feta cheese sold to retailers is a relevant product market and line of commerce within the meaning of Section 7 of the Clayton Act.

B. Relevant Geographic Markets

22. The relevant geographic markets for analyzing the effects of the proposed transaction on competition for feta and ricotta cheeses sold to retailers are best defined by reference to the locations of the retailers that purchase feta and ricotta cheeses in order to then sell those products to consumers.

23. This approach to defining the relevant geographic markets is appropriate because suppliers of feta and ricotta cheeses to retailers assess the competitive conditions in particular localities, including local demand for feta and ricotta cheeses, as well as local demand for the suppliers' own brands as compared to competing brands or to private label offerings. As a result, suppliers of feta and ricotta cheeses can charge different prices, or offer different levels of promotional funding, to retailers in different locations based on local competitive conditions. If targeted for a price increase or reduction in promotional funding, retailers in a given locality would be unlikely to be able to render such conduct unprofitable by purchasing feta or ricotta cheeses outside of the relevant geography and transporting it to their retail location.

24. Where ricotta and feta cheese suppliers can successfully vary prices and promotional funding based on retailer customer location, the goal of geographic market definition is to identify the area encompassing the location of potentially targeted customers. The relevant geographic markets identified below encompass the locations of retailers that would likely be targeted by suppliers for price increases as a result of the proposed transaction.

1. The Relevant Geographic Markets for Ricotta Cheese Sold to Retailers Are the New York Metro Market and the Florida Metro Markets

25. The relevant geographic markets for the sale of ricotta cheese to retailers that will be harmed by the proposed transaction are the New York Metro Market and the Florida Metro Markets. In each of these markets, Defendants compete vigorously with each other for sales of ricotta cheese to retailers that resell those products to consumers. Defendants' Polly-O and Galbani ricotta brands combined would account for approximately 70% of all ricotta cheese sales by retailers in the New York Metro Market and over 65% of all ricotta cheese sales by retailers in each of the Florida Metro Markets.

26. A hypothetical monopolist supplier of ricotta cheese to retailers in the New York Metro Market and in each of the Florida Metro Markets likely would increase its price by at least a small but significant and non-transitory amount. Therefore, the New York Metro Market and each of the Florida Metro Markets are relevant geographic markets and sections of the country within the meaning of Section 7 of the Clayton Act.

2. The Relevant Geographic Markets for Feta Cheese Sold to Retailers Are Individual Metropolitan and Surrounding Areas, but Can Be Analyzed on a National Basis for Convenience

27. The relevant geographic markets for the sale of feta cheese to retailers may be defined as narrowly as individual metropolitan and surrounding areas. A hypothetical monopolist supplier of feta cheese to retailers in any given metropolitan and surrounding area in the United States likely would find it profitable to increase its prices by at least a small but significant and non-transitory amount. Therefore, each metropolitan and surrounding area in the United States is a relevant geographic market and section of the country within the meaning of Section 7 of the Clayton Act.

28. In circumstances where competitive conditions are similar, it is appropriate to aggregate local markets into a larger relevant market for analytical convenience. The competitive conditions across the country are similar for the sale of feta cheese to retailers who purchase the cheese for resale to consumers. Kraft Heinz's Athenos feta and Lactalis's Président feta are the two top-selling feta cheese brands in the United States, and combined, the two brands would account for approximately 65% of all feta cheese sales by retailers nationally. While some regional brands of feta cheese exist, none place a significant competitive constraint on Defendants in any particular metropolitan and surrounding area. Therefore, it is appropriate to analyze competition for the sale of feta cheese to retailers on a national basis.

V. The Proposed Transaction Is Likely to Substantially Lessen Competition for the Sale of Ricotta and Feta Cheeses to Retailers

29. The proposed transaction would combine the two largest suppliers of ricotta cheese to retailers in the New York Metro Market and in each of the Florida Metro Markets, and the two largest suppliers of feta cheese to retailers nationally, resulting in a substantial increase in concentration in these markets.

30. The Supreme Court has held that mergers that significantly increase concentration in already concentrated markets are presumptively anticompetitive and therefore presumptively unlawful. To measure market concentration, courts often use the Herfindahl-Hirschman Index (''HHI'') as described in the *U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines.* HHIs range from 0 in markets with no concentration to 10,000 in markets where one firm has a 100% market share. According to the *Horizontal Merger Guidelines,* mergers that increase the HHI by more than 200 and result in an HHI above 2,500 in any relevant market or line of commerce are presumed to be anticompetitive and, therefore, unlawful.

31. The proposed transaction would eliminate substantial head-to-head competition between Defendants in both ricotta and feta cheese sales to retailers, leading to higher prices, lower quality, and less innovation for these products in the relevant markets.

32. The significant increase in market concentration that the proposed transaction would produce in the relevant markets, combined with the loss of head-to-head competition between Defendants, is likely to substantially lessen competition in violation of Section 7 of the Clayton Act.

A. The Proposed Transaction Is Presumptively Unlawful and Is Likely to Substantially Lessen Head-to-Head Competition for the Sale of Ricotta Cheese to Retailers

33. In the New York Metro Market, Defendants are the two largest suppliers of ricotta cheese to retailers, and their Polly-O and Galbani ricotta cheese brands combined would account for approximately 70% of all ricotta cheese sales by retailers in that market. In the New York Metro Market, the proposed transaction would increase the HHI by more than 2,400 points, resulting in a highly concentrated market with a post-acquisition HHI of more than 5,000 points. Thus, the proposed transaction is presumptively unlawful in the New York Metro Market.

34. In each of the Florida Metro Markets, Defendants are also the two largest suppliers of ricotta cheese to retailers, and their Polly-O and Galbani ricotta cheese brands combined would account for over 65% of all ricotta cheese sales by retailers. In each of the Florida Metro Markets, the proposed transaction would increase the HHI by more than 1,500 points, resulting in highly concentrated markets, each with a post-acquisition HHI of more than 4,400 points. Thus, the proposed transaction is presumptively unlawful in each of the Florida Metro Markets.

35. Defendants are particularly close competitors for ricotta cheese sold to retailers in the New York Metro Market and the Florida Metro Markets. They compete aggressively with each other on

pricing and promotions for ricotta cheese and in offering new and innovative products and features, such as double cream ricotta and packaging design.

36. The president of the Lactalis American Group Retail Division recognized this fact in February 2019, noting that, ''through aggressive pricing we managed to grow the Galbani share at the expense of [Kraft Heinz's] Poly-O [*sic*] from 2015 to 2018'' in the ricotta cheese category. Additionally, in January 2020, a Lactalis senior sales manager learned of an Easter price promotion on ricotta cheese that Polly-O was offering in the Northeast. Lactalis responded by improving its own Easter price promotion on ricotta cheese.

B. The Proposed Transaction Is Presumptively Unlawful and Is Likely to Substantially Lessen Head-to-Head Competition for the Sale of Feta Cheese to Retailers

37. Defendants are the two largest suppliers of feta cheese to retailers in the United States, and their Athenos and Président feta cheese brands combined would account for approximately 65% of all feta cheese sales by retailers nationally. In a national market for feta cheese sold by retailers, the proposed transaction would increase the HHI by more than 2,100 points, resulting in a highly concentrated market with a post-acquisition HHI of more than 4,300 points. Thus, the proposed transaction is presumptively unlawful.

38. Defendants are particularly close competitors for feta cheese sold to retailers in metropolitan and surrounding areas throughout the United States. Kraft Heinz's Athenos brand and Lactalis's Président brand are the two top-selling retail brands of feta cheese sold in the United States. A Lactalis executive referred to them as the ''two national leaders'' in feta cheese. They compete vigorously on prices, promotions, flavor, texture, variety (*e.g.,* fat free, traditional), and quality.

39. For example, in November 2020, a national sales manager at Kraft Heinz lamented that Kraft Heinz was ''in a really bad position'' at a supermarket chain because it ''lost the feta business in March when [we] were undercut by Lactalis.'' Similarly, a Lactalis marketing plan for feta cheese identified an objective of ''steal[ing] market share from [Kraft Heinz's] Athenos'' in 2021.

VI. Absence of Countervailing Factors

40. New entry and expansion by competitors are unlikely to be timely and sufficient enough to offset the proposed transaction's likely anticompetitive effects. Barriers to entering these markets are high and include the substantial time and expense required to build a brand's reputation and overcome existing consumer preferences through promotional and advertising activity as well as the substantial sunk costs needed to secure the distribution and placement of a new entrant's products in retail outlets (*e.g.,* paying slotting fees to obtain shelf space at supermarkets and other food retailers).

41. The proposed transaction is unlikely to generate verifiable, merger-specific efficiencies sufficient to reverse or outweigh the anticompetitive effects that are likely to occur as a result of the proposed transaction.

VII. Violations Alleged

42. The United States hereby incorporates the allegations of paragraphs 1 through 41 above as if set forth fully herein.

43. The proposed transaction is likely to substantially lessen competition in interstate trade and commerce, in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

44. Unless enjoined, the proposed transaction would likely have the following anticompetitive effects, among others:

a. Substantially lessening head-to-head competition between Defendants for the sale of feta cheese to retailers in the United States and ricotta cheese to retailers in the New York Metro Market and in each of the Florida Metro Markets;

b. substantially lessening competition generally in the market for feta cheese sold to retailers in the United States and ricotta cheese sold to retailers in the New York Metro Market and in each of the Florida Metro Markets;

c. causing prices to be higher than they would be otherwise for feta cheese sold to retailers in the United States and ricotta cheese sold to retailers in the New York Metro Market and in each of the Florida Metro Markets; and

d. reducing choice and innovation for feta cheese sold to retailers in the United States and ricotta cheese sold to retailers in the New York Metro Market and in each of the Florida Metro Markets.

VIII. Request for Relief

45. The United States requests that the Court:

a. Adjudge and decree the proposed transaction to be unlawful and in violation of Section 7 of the Clayton Act, 15 U.S.C. 18;

b. permanently enjoin and restrain Defendants and all persons acting on their behalf from carrying out the proposed transaction, or from entering into or carrying out any other contract, agreement, plan, or understanding, the effect of which would be to combine Defendants in the relevant markets alleged above;

c. award the United States its costs for this action; and

d. award the United States such other relief as the Court deems just and proper.

Dated: November 10, 2021

Respectfully submitted,

For Plaintiff United States of America

Richard A. Powers
Acting Assistant Attorney General, Antitrust Division.

Kathleen S. O'Neill
Senior Director of Investigations and Litigation, Antitrust Division.

Eric D. Welsh (DC Bar #998612)
Chief, Healthcare and Consumer Products Section, Antitrust Division.

Andrew J. Robinson (DC Bar #1008003)
Assistant Chief, Healthcare and Consumer Products Section, Antitrust Division.

Justin M. Dempsey* (DC Bar #425976)
Giancarlo R. Ambrogio (DC Bar #1736460)
Chris Hong
Garrett M. Liskey (DC Bar #1000937)
Natalie R. Melada
Attorneys for the United States, United States Department of Justice, Antitrust Division, Healthcare and Consumer Products Section, 450 Fifth Street NW, Suite 4100, Washington, DC 20530, Telephone: (202) 307–5815, Facsimile: (202) 307–5802, Email: Justin.Dempsey@usdoj.gov.

*LEAD ATTORNEY TO BE NOTICED

United States District Court for the District of Columbia

United States of America, Plaintiff, v.*B.S.A. S.A., LAG Holding, Inc.,* and *The Kraft Heinz Company,* Defendants.

Proposed Final Judgment

Whereas, Plaintiff, United States of America, filed its Complaint on November 10, 2021;

And whereas, the United States and Defendants, B.S.A. S.A., LAG Holding, Inc., and The Kraft Heinz Company, have consented to entry of this Final Judgment without the taking of testimony, without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against or admission by any party relating to any issue of fact or law;

And whereas, Defendants agree to make certain divestitures to remedy the loss of competition alleged in the Complaint;

And whereas, Defendants represent that the divestitures and other relief required by this Final Judgment can and will be made and that Defendants will not later raise a claim of hardship or difficulty as grounds for asking the Court to modify any provision of this Final Judgment;

Now therefore, it is ordered, adjudged, and decreed:

I. Jurisdiction

The Court has jurisdiction over the subject matter of and each of the parties to this action. The Complaint states a claim upon which relief may be granted against Defendants under Section 7 of the Clayton Act (15 U.S.C. 18).

II. Definitions

As used in this Final Judgment:

A. ''Acquirer'' or ''Acquirers'' means the entity or entities approved by the United States in its sole discretion to which Defendants divest any of the Divestiture Assets.

B. ''Acquirer of the Athenos Divestiture Assets'' means Emmi Roth or another entity approved by the United States in its sole discretion to which Defendants divest the Athenos Divestiture Assets.

C. ''Acquirer of the Polly-O Divestiture Assets'' means BelGioioso or another entity approved by the United States in its sole discretion to which Defendants divest the Polly-O Divestiture Assets.

D. ''Athenos Brand Name'' means Athenos and any other name that uses, incorporates, or references the Athenos name.

E. ''Athenos Divestiture Assets'' means all of Defendants' rights, titles, and interests in and to all property and assets, tangible and intangible, wherever located, relating to or used in connection with the Athenos Divestiture Business, including:

1. The Athenos Brand Name, including (a) the right to the exclusive use of the Athenos Brand Name in all sales channels (including the retail, foodservice, and ingredients or industrial channels), and (b) all other intellectual property owned, licensed, or sublicensed, either as licensor or licensee, including (i) patents, patent applications, and inventions and discoveries that may be patentable, (ii) registered and unregistered copyrights and copyright applications, and (iii) registered and unregistered trademarks, trade dress, service marks, trade names, and trademark applications;

2. all contracts, contractual rights, and customer relationships, and all other agreements, commitments, and understandings, including agreements with suppliers, manufacturers, co-packers, and retailers, teaming agreements, leases, and all outstanding offers or solicitations to enter into a similar arrangement;

3. all licenses, permits, certifications, approvals, consents, registrations, waivers, and authorizations, including those issued or granted by any governmental organization, and all pending applications or renewals;

4. all records and data, including (a) customer lists, accounts, sales, and credits records, (b) production, repair, maintenance, and performance records, (c) manuals and technical information Defendants provide to their own employees, customers, suppliers, agents, or licensees, (d) records and research data concerning historic and current research and development activities, including designs of experiments and the results of successful and unsuccessful designs and experiments, and (e) drawings, blueprints, and designs; and

5. all other intangible property, including (a) commercial names and d/b/a names, (b) technical information, including recipes and formulas, (c) computer software and related documentation, know-how, trade secrets, design protocols, specifications for materials, specifications for parts, specifications for devices, safety procedures (*e.g.,* for the handling of materials and substances), quality assurance and control procedures, (d) design tools and simulation capabilities, and (e) rights in internet websites and internet domain names.

Provided, however, that the assets specified in Paragraphs II.E.1–5 above do not include the Athenos Transitional Manufacturing Assets or the Athenos Transitional Services Contracts.

F. ''Athenos Divestiture Business'' means the worldwide business of the sale of Athenos Products by Kraft Heinz.

G. ''Athenos Personnel'' means all full-time, part-time, or contract employees of Kraft Heinz, wherever located, whose job responsibilities relate in any way to the Athenos Divestiture Assets, at any time between September 15, 2020, and the date on which the Athenos Divestiture Assets are divested. The United States, in its sole discretion, will resolve any disagreement relating to which employees are Athenos Personnel.

H. ''Athenos Products'' means any product that Kraft Heinz sold, sells, or has plans to sell under the Athenos Brand Name anywhere in the world.

I. ''Athenos Transitional Manufacturing Assets'' means:

1. Production lines numbers 25 and 26, which are used by the Athenos Divestiture Business for crumbling and packaging feta and are located at Kraft Heinz's facility at 1007 Townline Road, Wausau, Wisconsin 54403;

2. the feta packaging mold used to produce plastic feta lids and containers, which was purchased by Kraft Heinz in 2021 and is located at the facilities of RPC Bramlage-WIKO USA, Inc. in Morgantown, Pennsylvania; and

3. the contracts and agreements between Kraft Heinz and each of the following: (a) Agropur, dated January 13, 2021; (b) J. Rettenmaier USA LP, dated January 1, 2021; (c) International Paper Company, dated January 1, 2016, and last amended December 31, 2020; (d) Berry Global, Inc., dated April 1, 2014, supplemented September 22, 2014, and last amended August 1, 2019; (e) Weber Packaging Solutions, Inc., dated January 1, 2020; and (f) Bramlage, Inc. d/b/a RPC Bramlage Morgantown (the ''RPC Agreement''), dated October 23, 2017.

J. ''Athenos Transitional Services Contracts'' means the contracts and agreements between Kraft Heinz and each of the following: (a) Prairie Farms, dated November 3, 2020; (b) Great Lakes Cheese Company, Inc., dated January 1, 2021, and supplemented and amended on January 1, 2021; (c) Marathon Cheese Corporation, dated April 10, 2021, and supplemented on April 10, 2021; (d) Cedar's Mediterranean Foods, Inc., dated November 1, 2020, and supplemented on February 1, 2021; and (e) Saputo Cheese USA, Inc., dated November 1, 2020.

K. ''BelGioioso'' means BelGioioso Cheese, Inc., a Wisconsin corporation with its headquarters in Green Bay, Wisconsin, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

L. ''Divestiture Assets'' means the Athenos Divestiture Assets and the Polly-O Divestiture Assets.

M. ''Emmi Roth'' means Emmi Roth USA, Inc., a Wisconsin corporation with its headquarters in Fitchburg, Wisconsin, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

N. ''Including'' means including, but not limited to.

O. ''Kraft Heinz'' means Defendant The Kraft Heinz Company, a Delaware corporation with its co-headquarters in Pittsburgh, Pennsylvania and Chicago, Illinois, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint

ventures, and their directors, officers, managers, agents, and employees.

P. ''Lactalis'' means Defendant B.S.A. S.A., a French corporation with its headquarters in Laval, France, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

Q. ''LAG Holding'' means Defendant LAG Holding, Inc., a wholly-owned subsidiary of Lactalis and a Delaware corporation with its headquarters in Buffalo, New York, its successors and assigns, and its subsidiaries, including Lactalis American Group, Inc., divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

R. ''Polly-O Brand Name'' means Polly-O and any other name that uses, incorporates, or references the Polly-O name.

S. ''Polly-O Divestiture Assets'' means all of Defendants' rights, titles, and interests in and to all property and assets, tangible and intangible, wherever located, relating to or used in connection with the Polly-O Divestiture Business, including:

1. The Polly-O Brand Name, including (a) the right to the exclusive use of the Polly-O Brand Name in all sales channels (including the retail, foodservice, and ingredients or industrial channels), and (b) all other intellectual property owned, licensed, or sublicensed, either as licensor or licensee, including (i) patents, patent applications, and inventions and discoveries that may be patentable, (ii) registered and unregistered copyrights and copyright applications, and (iii) registered and unregistered trademarks, trade dress, service marks, trade names, and trademark applications;

2. the Shared Recipes License;

3. all contracts, contractual rights, and customer relationships, and all other agreements, commitments, and understandings, including agreements with suppliers, manufacturers, co-packers, and retailers, teaming agreements, leases, and all outstanding offers or solicitations to enter into a similar arrangement;

4. all licenses, permits, certifications, approvals, consents, registrations, waivers, and authorizations, including those issued or granted by any governmental organization, and all pending applications or renewals;

5. all records and data, including (a) customer lists, accounts, sales, and credits records, (b) production, repair, maintenance, and performance records, (c) manuals and technical information Defendants provide to their own employees, customers, suppliers, agents, or licensees, (d) records and research data concerning historic and current research and development activities, including designs of experiments and the results of successful and unsuccessful designs and experiments, and (e) drawings, blueprints, and designs; and

6. all other intangible property, including (a) commercial names and d/b/a names, (b) technical information, (c) computer software and related documentation, know-how, trade secrets, design protocols, specifications for materials, specifications for parts, specifications for devices, safety procedures (*e.g.,* for the handling of materials and substances), quality assurance and control procedures, (d) design tools and simulation capabilities, and (e) rights in internet websites and internet domain names.

Provided, however, that the assets specified in Paragraphs II.S.1–6 above do not include any ownership of the intellectual property licensed through the Shared Recipes License or the Polly-O Excluded Contracts.

T. ''Polly-O Divestiture Business'' means the worldwide business of the sale of Polly-O Products by Kraft Heinz.

U. ''Polly-O Excluded Contracts'' means the contracts and agreements between Kraft Heinz and each of the following: (a) Foremost Farms USA Cooperative, dated October 8, 2020; (b) Marathon Cheese Corporation, dated April 10, 2021, and supplemented on April 10, 2021; (c) Saputo Cheese USA Inc., dated November 1, 2020; (d) Amcor Flexibles North America, Inc. (fka Bemis Company, Inc.), dated January 1, 2015, entered into initially between H.J. Heinz Supply Chain Europe B.V. and Bemis Company, Inc., and last amended November 1, 2020; (e) International Paper Company, dated January 1, 2016, and last amended December 31, 2020; (f) Berry Global, Inc., dated April 1, 2014, supplemented September 22, 2014, and last amended August 1, 2019; (g) Transcontinental US LLC, dated January 1, 2019; and (h) J. Rettenmaier USA LP, dated January 1, 2021.

V. ''Polly-O Personnel'' means all full-time, part-time, or contract employees of Kraft Heinz, wherever located, whose job responsibilities relate in any way to the Polly-O Divestiture Assets, at any time between September 15, 2020, and the date on which the Polly-O Divestiture Assets are divested. The United States, in its sole discretion, will resolve any disagreement relating to which employees are Polly-O Personnel.

W. ''Polly-O Products'' means any product that Kraft Heinz sold, sells, or has plans to sell under the Polly-O Brand Name anywhere in the world.

X. ''Shared Recipes License'' means a perpetual, royalty-free, paid-up, irrevocable, worldwide, non-exclusive license to the formulas, recipes and related trade secrets, know-how, confidential business information and related data that, on or prior to the date of the signing of the Asset Preservation and Hold Separate Stipulation and Order by Defendants, were used by Kraft Heinz for the production of cheese sold under both (i) the Polly-O Brand Name and (ii) any name other than the Polly-O Brand Name.

Y. ''Transaction'' means the definitive agreement that Lactalis and Kraft Heinz entered into on September 15, 2020, for the acquisition by Lactalis of, among other assets, Kraft Heinz's natural, grated, cultured, and specialty cheese businesses in the United States.

III. Applicability

A. This Final Judgment applies to Lactalis, LAG Holding, and Kraft Heinz, as defined above, and all other persons in active concert or participation with any Defendant who receive actual notice of this Final Judgment.

B. If, prior to complying with Section IV, Section V, and Section VI of this Final Judgment, Defendants sell or otherwise dispose of all or substantially all of their assets or of business units that include any of the Divestiture Assets, Defendants must require any purchaser to be bound by the provisions of this Final Judgment. Defendants need not obtain such an agreement from Acquirers.

IV. Divestiture of the Athenos Divestiture Assets

A. Defendants are ordered and directed, within 30 calendar days after the Court's entry of the Asset Preservation and Hold Separate Stipulation and Order in this matter, to divest the Athenos Divestiture Assets in a manner consistent with this Final Judgment to Emmi Roth or another Acquirer acceptable to the United States, in its sole discretion. The United States, in its sole discretion, may agree to one or more extensions of this time period not to exceed 60 calendar days in total and will notify the Court of any extensions.

B. Defendants must use best efforts to divest the Athenos Divestiture Assets as expeditiously as possible. Defendants must take no action that would jeopardize the completion of the divestiture ordered by the Court, including any action to impede the permitting, operation, or divestiture of the Athenos Divestiture Assets.

C. Unless the United States otherwise consents in writing, divestiture pursuant to this Final Judgment must include the entire Athenos Divestiture Assets and must be accomplished in such a way as to satisfy the United States, in its sole discretion, that the Athenos Divestiture Assets can and will be used by Acquirer of the Athenos Divestiture Assets as part of a viable, ongoing business of selling feta cheese to retailers and that the divestiture to Acquirer of the Athenos Divestiture Assets will remedy the competitive harm in the market for selling feta cheese to retailers alleged in the Complaint.

D. The divestiture of the Athenos Divestiture Assets must be made to an Acquirer that, in the United States' sole judgment, has the intent and capability, including the necessary managerial, operational, technical, and financial capability, to compete effectively in the sale of feta cheese to retailers.

E. The divestiture of the Athenos Divestiture Assets must be accomplished in a manner that satisfies the United States, in its sole discretion, that none of the terms of any agreement between Acquirer of the Athenos Divestiture Assets and Defendants gives Defendants the ability unreasonably to raise costs for Acquirer of the Athenos Divestiture Assets, to lower the efficiency of Acquirer of the Athenos Divestiture Assets, or otherwise interfere in the ability of Acquirer of the Athenos Divestiture Assets to compete effectively in the sale of feta cheese to retailers.

F. In the event Defendants are attempting to divest the Athenos Divestiture Assets to an Acquirer other than Emmi Roth, Defendants promptly must make known, by usual and customary means, the availability of the Athenos Divestiture Assets. Defendants must inform any person making an inquiry relating to a possible purchase of the Athenos Divestiture Assets that the Athenos Divestiture Assets are being divested in accordance with this Final Judgment and must provide that person with a copy of this Final Judgment. Defendants must offer to furnish to all prospective Acquirers of the Athenos Divestiture Assets, subject to customary confidentiality assurances, all information and documents relating to the Athenos Divestiture Assets that are customarily provided in a due diligence process; *provided, however,* that Defendants need not provide information or documents subject to the attorney-client privilege or work-product doctrine. Defendants must make all information and documents available to the United States at the same time that the information and documents are made available to any other person.

G. Defendants must provide prospective Acquirers of the Athenos Divestiture Assets with (1) access to make inspections of the Athenos Divestiture Assets; (2) access to all environmental, zoning, and other permitting documents and information relating to the Athenos Divestiture Assets; and (3) access to all financial, operational, or other documents and information relating to the Athenos Divestiture Assets that would customarily be provided as part of a due diligence process. Defendants also must disclose all encumbrances on any part of the Athenos Divestiture Assets, including on intangible property.

H. Defendants must cooperate with and assist Acquirer of the Athenos Divestiture Assets in identifying and, at the option of Acquirer of the Athenos Divestiture Assets, in hiring all Athenos Personnel, including:

1. Within 10 business days following the filing of the Complaint in this matter, Defendants must identify all Athenos Personnel to Acquirer of the Athenos Divestiture Assets and the United States, including by providing organization charts covering all Athenos Personnel.

2. Within 10 business days following receipt of a request by Acquirer of the Athenos Divestiture Assets or the United States, Defendants must provide to Acquirer of the Athenos Divestiture Assets and the United States additional information relating to Athenos Personnel, including name, job title, reporting relationships, past experience, responsibilities, training and educational histories, relevant certifications, and job performance evaluations. Defendants must also provide to Acquirer of the Athenos Divestiture Assets and the United States information relating to current and accrued compensation and benefits of Athenos Personnel, including most recent bonuses paid, aggregate annual compensation, current target or guaranteed bonus, if any, any retention agreement or incentives, and any other payments due, compensation or benefits accrued, or promises made to the Athenos Personnel. If Defendants are barred by any applicable law from providing any of this information, Defendants must provide, within 10 business days following receipt of the request, the requested information to the full extent permitted by law and also must provide a written explanation of Defendants' inability to provide the remaining information, including specifically identifying the provisions of the applicable laws.

3. At the request of Acquirer of the Athenos Divestiture Assets, Defendants must promptly make Athenos Personnel available for private interviews with Acquirer of the Athenos Divestiture Assets during normal business hours at a mutually agreeable location.

4. Defendants must not interfere with any effort by Acquirer of the Athenos Divestiture Assets to employ any Athenos Personnel. Interference includes offering to increase the compensation or improve the benefits of Athenos Personnel unless (a) the offer is part of a company-wide increase in compensation or improvement in benefits that was announced prior to September 15, 2020, or (b) the offer is approved by the United States in its sole discretion. Defendants' obligations under this Paragraph will expire six months after the date on which the Athenos Divestiture Assets are divested.

5. For Athenos Personnel who elect employment with Acquirer of the Athenos Divestiture Assets either (a) before the date on which a transition services contract entered into pursuant to Paragraph IV.P is terminated or expires, or (b) within three months after the date on which such a contract is terminated or expires, Defendants must waive all non-compete and non-disclosure agreements; vest and pay to the Athenos Personnel (or to Acquirer of the Athenos Divestiture Assets for payment to the employee) on a prorated basis any bonuses, incentives, other salary, benefits, or other compensation fully or partially accrued at the time of the transfer of the employee to Acquirer of the Athenos Divestiture Assets; vest any unvested pension and other equity rights; and provide all other benefits that those Athenos Personnel otherwise would have been provided had the Athenos Personnel continued employment with Defendants, including any retention bonuses or payments. Defendants may maintain reasonable restrictions on disclosure by Athenos Personnel of Defendants' proprietary non-public information that is unrelated to the Athenos Divestiture Assets and not otherwise required to be disclosed by this Final Judgment.

6. For a period of 12 months from the date on which the Athenos Divestiture Assets are divested, Defendants may not solicit to rehire Athenos Personnel who were hired by Acquirer of the Athenos Divestiture Assets either (a) before the date on which a transition services contract entered into pursuant to Paragraph IV.P is terminated or expires, or (b) within three months after the date on which such a contract is terminated

or expires, unless an individual is terminated or laid off by Acquirer of the Athenos Divestiture Assets or Acquirer of the Athenos Divestiture Assets agrees in writing that Defendants may solicit to re-hire that individual. Nothing in this Paragraph prohibits Defendants from advertising employment openings using general solicitations or advertisements and re-hiring Athenos Personnel who apply for an employment opening through a general solicitation or advertisement.

I. Defendants must warrant to Acquirer of the Athenos Divestiture Assets that (1) the Athenos Divestiture Assets will be operational and without material defect on the date of their transfer to Acquirer of the Athenos Divestiture Assets; (2) there are no material defects in the environmental, zoning, or other permits relating to the operation of the Athenos Divestiture Assets; and (3) Defendants have disclosed all encumbrances on any part of the Athenos Divestiture Assets, including on intangible property. Following the sale of the Athenos Divestiture Assets, Defendants must not undertake, directly or indirectly, challenges to the environmental, zoning, or other permits relating to the operation of the Athenos Divestiture Assets.

J. Defendants must assign, subcontract, or otherwise transfer all contracts, agreements, and customer relationships (or portions of such contracts, agreements, and customer relationships) included in the Athenos Divestiture Assets, including all supply and sales contracts and co-packing and packaging supplier agreements, to Acquirer of the Athenos Divestiture Assets; *provided, however,* that for any contract or agreement that requires the consent of another party to assign, subcontract, or otherwise transfer, Defendants must use best efforts to accomplish the assignment, subcontracting, or transfer. Defendants must not interfere with any negotiations between Acquirer of the Athenos Divestiture Assets and a contracting party.

K. Defendants must, at the option of the Acquirer of the Athenos Divestiture Assets, and subject to the approval by the United States in its sole discretion, assign, subcontract, or otherwise transfer any of the Athenos Transitional Services Contracts to Acquirer of the Athenos Divestiture Assets upon request of the Acquirer of the Athenos Divestiture Assets either at the time of the divestiture of the Athenos Divestiture Assets or at any time prior to the expiration or termination of a transition services contract entered into pursuant to Paragraph IV.P; *provided, however,* that for any contract or agreement that requires the consent of another party to assign, subcontract, or otherwise transfer, Defendants must use best efforts to accomplish the assignment, subcontracting, or transfer. Defendants must not interfere with any negotiations between Acquirer of the Athenos Divestiture Assets and a contracting party.

L. Defendants must use best efforts to assist Acquirer of the Athenos Divestiture Assets to obtain all necessary licenses, registrations, and permits to operate the Athenos Divestiture Business. Until Acquirer of the Athenos Divestiture Assets obtains the necessary licenses, registrations, and permits, Defendants must provide Acquirer of the Athenos Divestiture Assets with the benefit of Defendants' licenses, registrations, and permits to the full extent permissible by law.

M. At the option of Acquirer of the Athenos Divestiture Assets, and subject to approval by the United States in its sole discretion, on or before the date on which the Athenos Divestiture Assets are divested, Defendants must enter into a supply contract or contracts for the processing and packaging of Athenos Products sufficient to meet the needs of Acquirer of the Athenos Divestiture Assets, as determined by Acquirer of the Athenos Divestiture Assets, for a period of up to two years, on terms and conditions reasonably related to market conditions for the processing and packaging of Athenos Products. Any amendment to or modification of any provision of any such supply contract is subject to approval by the United States, in its sole discretion. The United States, in its sole discretion, may approve one or more extensions of any supply contract, for a total of up to an additional 12 months. If Acquirer of the Athenos Divestiture Assets seeks an extension of the term of any supply contract, Defendants must notify the United States in writing at least three months prior to the date the supply contract expires. Acquirer of the Athenos Divestiture Assets may terminate a supply contract, or any portion of a supply contract, without cost or penalty at any time upon commercially reasonable written notice. The employees of Defendants tasked with providing services pursuant to a supply contract must not share any competitively sensitive information of Acquirer of the Athenos Divestiture Assets with any other employee of Defendants.

N. At the option of Acquirer of the Athenos Divestiture Assets, and subject to approval by the United States in its sole discretion, Defendants may, for the sole purpose of fulfilling any supply contract required by Paragraph IV.M of this Final Judgment, retain the Athenos Transitional Manufacturing Assets until the earlier of (1) 60 calendar days after Acquirer of the Athenos Divestiture Assets terminates the supply contract or contracts required by Paragraph IV.M of this Final Judgment or (2) 60 calendar days following the expiration of any supply contract or contracts required by Paragraph IV.M of this Final Judgment, after which Defendants must sell and transfer to Acquirer of the Athenos Divestiture Assets the Athenos Transitional Manufacturing Assets on terms and conditions reasonably related to market conditions for such manufacturing assets.

O. Defendants must warrant to Acquirer of the Athenos Divestiture Assets that (1) the Athenos Transitional Manufacturing Assets will be operational and without material defect on the date of their transfer to Acquirer of the Athenos Divestiture Assets; (2) there are no material defects in the environmental, zoning, or other permits relating to the operation of the Athenos Transitional Manufacturing Assets; and (3) Defendants have disclosed all encumbrances on any part of the Athenos Transitional Manufacturing Assets, including on intangible property. Following the sale of the Athenos Transitional Manufacturing Assets, Defendants must not undertake, directly or indirectly, challenges to the environmental, zoning, or other permits relating to the operation of the Athenos Transitional Manufacturing Assets.

P. At the option of Acquirer of the Athenos Divestiture Assets, and subject to approval by the United States in its sole discretion, on or before the date on which the Athenos Divestiture Assets are divested, Defendants must enter into a contract to provide transition services for back office, human resources, accounting, information technology services and support, facilitating repacking, warehousing, transportation, and by making personnel available to assist Acquirer of the Athenos Divestiture Assets for a period of up to six months on terms and conditions reasonably related to market conditions for the provision of the transition services. Any amendment to or modification of any provision of a contract to provide transition services is subject to approval by the United States, in its sole discretion. The United States, in its sole discretion, may approve one or more extensions of any contract for transition services, for a total of up to an additional six months. If Acquirer of the Athenos Divestiture Assets seeks an

extension of the term of any contract for transition services, Defendants must notify the United States in writing at least 30 days prior to the date the contract expires. Acquirer of the Athenos Divestiture Assets may terminate a contract for transition services, or any portion of a contract for transition services, without cost or penalty at any time upon commercially reasonable written notice. The employees of Defendants tasked with providing transition services must not share any competitively sensitive information of Acquirer of the Athenos Divestiture Assets with any other employee of Defendants.

Q. If any term of an agreement between Defendants and Acquirer of the Athenos Divestiture Assets, including an agreement to effectuate the divestiture of the Athenos Divestiture Assets required by this Final Judgment, varies from a term of this Final Judgment, to the extent that Defendants cannot fully comply with both, this Final Judgment determines Defendants' obligations.

V. Divestiture of the Polly-O Divestiture Assets

A. Defendants are ordered and directed, within 30 calendar days after the Court's entry of the Asset Preservation and Hold Separate Stipulation and Order in this matter, to divest the Polly-O Divestiture Assets in a manner consistent with this Final Judgment to BelGioioso or another Acquirer acceptable to the United States, in its sole discretion. The United States, in its sole discretion, may agree to one or more extensions of this time period not to exceed 60 calendar days in total and will notify the Court of any extensions.

B. Defendants must use best efforts to divest the Polly-O Divestiture Assets as expeditiously as possible. Defendants must take no action that would jeopardize the completion of the divestiture ordered by the Court, including any action to impede the permitting, operation, or divestiture of the Polly-O Divestiture Assets.

C. Unless the United States otherwise consents in writing, divestiture pursuant to this Final Judgment must include the entire Polly-O Divestiture Assets and must be accomplished in such a way as to satisfy the United States, in its sole discretion, that the Polly-O Divestiture Assets can and will be used by Acquirer of the Polly-O Divestiture Assets as part of a viable, ongoing business of selling ricotta cheese to retailers, and that the divestiture to Acquirer of the Polly-O Divestiture Assets will remedy the competitive harm in the market for selling ricotta cheese to retailers alleged in the Complaint.

D. The divestiture of the Polly-O Divestiture Assets must be made to an Acquirer that, in the United States' sole judgment, has the intent and capability, including the necessary managerial, operational, technical, and financial capability, to compete effectively in the sale of ricotta cheese to retailers.

E. The divestiture of the Polly-O Divestiture Assets must be accomplished in a manner that satisfies the United States, in its sole discretion, that none of the terms of any agreement between Acquirer of the Polly-O Divestiture Assets and Defendants gives Defendants the ability unreasonably to raise costs for Acquirer of the Polly-O Divestiture Assets, to lower the efficiency of Acquirer of the Polly-O Divestiture Assets, or otherwise interfere in the ability of Acquirer of the Polly-O Divestiture Assets to compete effectively in the sale of ricotta cheese to retailers.

F. In the event Defendants are attempting to divest the Polly-O Divestiture Assets to an Acquirer other than BelGioioso, Defendants promptly must make known, by usual and customary means, the availability of the Polly-O Divestiture Assets. Defendants must inform any person making an inquiry relating to a possible purchase of the Polly-O Divestiture Assets that the Polly-O Divestiture Assets are being divested in accordance with this Final Judgment and must provide that person with a copy of this Final Judgment. Defendants must offer to furnish to all prospective Acquirers of the Polly-O Divestiture Assets, subject to customary confidentiality assurances, all information and documents relating to the Polly-O Divestiture Assets that are customarily provided in a due diligence process; *provided, however,* that Defendants need not provide information or documents subject to the attorney-client privilege or work-product doctrine. Defendants must make all information and documents available to the United States at the same time that the information and documents are made available to any other person.

G. Defendants must provide prospective Acquirers of the Polly-O Divestiture Assets with (1) access to make inspections of the Polly-O Divestiture Assets; (2) access to all environmental, zoning, and other permitting documents and information relating to the Polly-O Divestiture Assets; and (3) access to all financial, operational, or other documents and information relating to the Polly-O Divestiture Assets that would customarily be provided as part of a due diligence process. Defendants also must disclose all encumbrances on any part of the Polly-O Divestiture Assets, including on intangible property.

H. Defendants must cooperate with and assist Acquirer of the Polly-O Divestiture Assets in identifying and, at the option of Acquirer of the Polly-O Divestiture Assets, in hiring all Polly-O Personnel, including:

1. Within 10 business days following the filing of the Complaint in this matter, Defendants must identify all Polly-O Personnel to Acquirer of the Polly-O Divestiture Assets and the United States, including by providing organization charts covering all Polly-O Personnel.

2. Within 10 business days following receipt of a request by Acquirer of the Polly-O Divestiture Assets or the United States, Defendants must provide to Acquirer of the Polly-O Divestiture Assets and the United States additional information relating to Polly-O Personnel, including name, job title, reporting relationships, past experience, responsibilities, training and educational histories, relevant certifications, and job performance evaluations. Defendants must also provide to Acquirer of the Polly-O Divestiture Assets and the United States information relating to current and accrued compensation and benefits of Polly-O Personnel, including most recent bonuses paid, aggregate annual compensation, current target or guaranteed bonus, if any, any retention agreement or incentives, and any other payments due, compensation or benefits accrued, or promises made to the Polly-O Personnel. If Defendants are barred by any applicable law from providing any of this information, Defendants must provide, within 10 business days following receipt of the request, the requested information to the full extent permitted by law and also must provide a written explanation of Defendants' inability to provide the remaining information, including specifically identifying the provisions of the applicable laws.

3. At the request of Acquirer of the Polly-O Divestiture Assets, Defendants must promptly make Polly-O Personnel available for private interviews with Acquirer of the Polly-O Divestiture Assets during normal business hours at a mutually agreeable location.

4. Defendants must not interfere with any effort by Acquirer of the Polly-O Divestiture Assets to employ any Polly-O Personnel. Interference includes offering to increase the compensation or improve the benefits of Polly-O

Personnel unless (a) the offer is part of a company-wide increase in compensation or improvement in benefits that was announced prior to September 15, 2020, or (b) the offer is approved by the United States in its sole discretion. Defendants' obligations under this Paragraph will expire six months after the date on which the Polly-O Divestiture Assets are divested.

5. For Polly-O Personnel who elect employment with Acquirer of the Polly-O Divestiture Assets either (a) before the date on which a transition services contract entered into pursuant to Paragraph V.N is terminated or expires, or (b) within three months after the date on which such a contract is terminated or expires, Defendants must waive all non-compete and non-disclosure agreements; vest and pay to the Polly-O Personnel (or to Acquirer of the Polly-O Divestiture Assets for payment to the employee) on a prorated basis any bonuses, incentives, other salary, benefits, or other compensation fully or partially accrued at the time of the transfer of the employee to Acquirer of the Polly-O Divestiture Assets; vest any unvested pension and other equity rights; and provide all other benefits that those Polly-O Personnel otherwise would have been provided had the Polly-O Personnel continued employment with Defendants, including any retention bonuses or payments. Defendants may maintain reasonable restrictions on disclosure by Polly-O Personnel of Defendants' proprietary non-public information that is unrelated to the Polly-O Divestiture Assets and not otherwise required to be disclosed by this Final Judgment.

6. For a period of 12 months from the date on which the Polly-O Divestiture Assets are divested, Defendants may not solicit to rehire Polly-O Personnel who were hired by Acquirer of the Polly-O Divestiture Assets either (a) before the date on which a transition services contract entered into pursuant to Paragraph V.N is terminated or expires, or (b) within three months after the date on which such a contract is terminated or expires, unless an individual is terminated or laid off by Acquirer of the Polly-O Divestiture Assets or Acquirer of the Polly-O Divestiture Assets agrees in writing that Defendants may solicit to re-hire that individual. Nothing in this Paragraph prohibits Defendants from advertising employment openings using general solicitations or advertisements and re-hiring Polly-O Personnel who apply for an employment opening through a general solicitation or advertisement.

I. Defendants must warrant to Acquirer of the Polly-O Divestiture Assets that (1) the Polly-O Divestiture Assets will be operational and without material defect on the date of their transfer to Acquirer of the Polly-O Divestiture Assets; (2) there are no material defects in the environmental, zoning, or other permits relating to the operation of the Polly-O Divestiture Assets; and (3) Defendants have disclosed all encumbrances on any part of the Polly-O Divestiture Assets, including on intangible property. Following the sale of the Polly-O Divestiture Assets, Defendants must not undertake, directly or indirectly, challenges to the environmental, zoning, or other permits relating to the operation of the Polly-O Divestiture Assets.

J. Defendants must assign, subcontract, or otherwise transfer all contracts, agreements, and customer relationships (or portions of such contracts, agreements, and customer relationships) included in the Polly-O Divestiture Assets, including all supply and sales contracts and co-packing and packaging supply agreements, to Acquirer of the Polly-O Divestiture Assets; *provided, however,* that for any contract or agreement that requires the consent of another party to assign, subcontract, or otherwise transfer, Defendants must use best efforts to accomplish the assignment, subcontracting, or transfer. Defendants must not interfere with any negotiations between Acquirer of the Polly-O Divestiture Assets and a contracting party.

K. In the event Defendants are attempting to divest the Polly-O Divestiture Assets to an Acquirer other than BelGioioso, Defendants must, as the option of Acquirer of the Polly-O Divestiture Assets, and subject to the approval by the United States in its sole discretion, assign, subcontract, or otherwise transfer any of the Polly-O Excluded Contracts to Acquirer of the Polly-O Divestiture Assets; *provided, however,* that for any contract or agreement that requires the consent of another party to assign, subcontract, or otherwise transfer, Defendants must use best efforts to accomplish the assignment, subcontracting, or transfer. Defendants must not interfere with any negotiations between Acquirer of the Polly-O Divestiture Assets and a contracting party.

L. Defendants must use best efforts to assist Acquirer of the Polly-O Divestiture Assets to obtain all necessary licenses, registrations, and permits to operate the Polly-O Divestiture Business. Until Acquirer of the Polly-O Divestiture Assets obtains the necessary licenses, registrations, and permits, Defendants must provide Acquirer of the Polly-O Divestiture Assets with the benefit of Defendants' licenses, registrations, and permits to the full extent permissible by law.

M. At the option of Acquirer of the Polly-O Divestiture Assets, and subject to approval by the United States in its sole discretion, on or before the date on which the Polly-O Divestiture Assets are divested, Defendants must enter into a supply contract or contracts for the production and packaging of Polly-O Products sufficient to meet the needs of Acquirer of the Polly-O Divestiture Assets, as determined by Acquirer of the Polly-O Divestiture Assets, for a period of up to 12 months, on terms and conditions reasonably related to market conditions for the production and packaging of Polly-O Products. Any amendment to or modification of any provision of any such supply contract is subject to approval by the United States, in its sole discretion. The United States, in its sole discretion, may approve one or more extensions of any supply contract, for a total of up to an additional 12 months. If Acquirer of the Polly-O Divestiture Assets seeks an extension of the term of any supply contract, Defendants must notify the United States in writing at least three months prior to the date the supply contract expires. Acquirer of the Polly-O Divestiture Assets may terminate a supply contract, or any portion of a supply contract, without cost or penalty at any time upon commercially reasonable written notice. The employees of Defendants tasked with providing services pursuant to a supply contract must not share any competitively sensitive information of Acquirer of the Polly-O Divestiture Assets with any other employee of Defendants.

N. At the option of Acquirer of the Polly-O Divestiture Assets, and subject to approval by the United States in its sole discretion, on or before the date on which the Polly-O Divestiture Assets are divested, Defendants must enter into a contract to provide transition services for back office, human resources, accounting, information technology services and support, facilitating repacking, warehousing, transportation, and by making personnel available to assist Acquirer of the Polly-O Divestiture Assets for a period of up to six months on terms and conditions reasonably related to market conditions for the provision of the transition services. Any amendment to or modification of any provision of a contract to provide transition services is subject to approval by the United States, in its sole discretion. The United States,

in its sole discretion, may approve one or more extensions of any contract for transition services, for a total of up to an additional six months. If Acquirer of the Polly-O Divestiture Assets seeks an extension of the term of any contract for transition services, Defendants must notify the United States in writing at least 30 days prior to the date the contract expires. Acquirer of the Polly-O Divestiture Assets may terminate a contract for transition services, or any portion of a contract for transition services, without cost or penalty at any time upon commercially reasonable written notice. The employees of Defendants tasked with providing transition services must not share any competitively sensitive information of Acquirer of the Polly-O Divestiture Assets with any other employee of Defendants.

O. If any term of an agreement between Defendants and Acquirer of the Polly-O Divestiture Assets, including an agreement to effectuate the divestiture of the Polly-O Divestiture Assets required by this Final Judgment, varies from a term of this Final Judgment, to the extent that Defendants cannot fully comply with both, this Final Judgment determines Defendants' obligations.

VI. Appointment of Divestiture Trustee

A. If Defendants have not divested all of the Divestiture Assets within the periods specified in Paragraphs IV.A and V.A, Defendants must immediately notify the United States of that fact in writing. Upon application of the United States, which Defendants may not oppose, the Court will appoint a divestiture trustee selected by the United States and approved by the Court to effect the divestiture of any of the Divestiture Assets that have not been sold during the time periods specified in Paragraphs IV.A and V.A.

B. After the appointment of a divestiture trustee by the Court, only the divestiture trustee will have the right to sell those Divestiture Assets that the divestiture trustee has been appointed to sell. The divestiture trustee will have the power and authority to accomplish the divestiture(s) to an Acquirer(s) acceptable to the United States, in its sole discretion, at a price and on terms obtainable through reasonable effort by the divestiture trustee, subject to the provisions of Sections IV, V, VI, and VII of this Final Judgment, and will have other powers as the Court deems appropriate. The divestiture trustee must sell the relevant Divestiture Assets as quickly as possible.

C. Defendants may not object to a sale by the divestiture trustee on any ground other than malfeasance by the divestiture trustee. Objections by Defendants must be conveyed in writing to the United States and the divestiture trustee within 10 calendar days after the divestiture trustee has provided the notice of proposed divestiture required by Section VII.

D. The divestiture trustee will serve at the cost and expense of Defendants pursuant to a written agreement, on terms and conditions, including confidentiality requirements and conflict of interest certifications, approved by the United States in its sole discretion.

E. The divestiture trustee may hire at the cost and expense of Defendants any agents or consultants, including investment bankers, attorneys, and accountants, that are reasonably necessary in the divestiture trustee's judgment to assist with the divestiture trustee's duties. These agents or consultants will be accountable solely to the divestiture trustee and will serve on terms and conditions, including confidentiality requirements and conflict-of-interest certifications, approved by the United States in its sole discretion.

F. The compensation of the divestiture trustee and agents or consultants hired by the divestiture trustee must be reasonable in light of the value of the Divestiture Assets and based on a fee arrangement that provides the divestiture trustee with incentives based on the price and terms of the divestiture and the speed with which it is accomplished. If the divestiture trustee and Defendants are unable to reach agreement on the divestiture trustee's compensation or other terms and conditions of engagement within 14 calendar days of the appointment of the divestiture trustee by the Court, the United States, in its sole discretion, may take appropriate action, including by making a recommendation to the Court. Within three business days of hiring an agent or consultant, the divestiture trustee must provide written notice of the hiring and rate of compensation to Defendants and the United States.

G. The divestiture trustee must account for all monies derived from the sale of the Divestiture Assets sold by the divestiture trustee and all costs and expenses incurred. Within 30 calendar days of the date on which any divestiture overseen by the divestiture trustee is completed, the divestiture trustee must submit that accounting to the Court for approval. After approval by the Court of the divestiture trustee's accounting, including fees for unpaid services and those of agents or consultants hired by the divestiture trustee, all remaining money must be paid to Defendants and the trust will then be terminated.

H. Defendants must use best efforts to assist the divestiture trustee to accomplish the required divestiture(s). Subject to reasonable protection for trade secrets, other confidential research, development, or commercial information, or any applicable privileges, Defendants must provide the divestiture trustee and agents or consultants retained by the divestiture trustee with full and complete access to all personnel, books, records, and facilities of the relevant Divestiture Assets. Defendants also must provide or develop financial and other information relevant to the Divestiture Assets that the divestiture trustee may reasonably request. Defendants must not take any action to interfere with or to impede the divestiture trustee's accomplishment of the divestiture(s).

I. The divestiture trustee must maintain complete records of all efforts made to sell any of the Divestiture Assets that have not been sold during the time periods specified in Paragraphs IV.A and V.A, including by filing monthly reports with the United States setting forth the divestiture trustee's efforts to accomplish the divestiture(s) ordered by this Final Judgment. The reports must include the name, address, and telephone number of each person who, during the preceding month, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring any interest in the Divestiture Assets that the divestiture trustee has been appointed to sell and must describe in detail each contact.

J. If the divestiture trustee has not accomplished the divestiture(s) ordered by this Final Judgment within six months of appointment, the divestiture trustee must promptly provide the United States with a report setting forth: (1) The divestiture trustee's efforts to accomplish the required divestiture(s); (2) the reasons, in the divestiture trustee's judgment, why the required divestiture(s) has not been accomplished; and (3) the divestiture trustee's recommendations for completing the divestiture(s). Following receipt of that report, the United States may make additional recommendations to the Court. The Court thereafter may enter such orders as it deems appropriate to carry out the purpose of this Final Judgment, which may include extending the trust and the term of the divestiture trustee's appointment by a period requested by the United States.

K. The divestiture trustee will serve until divestiture of all Divestiture Assets is completed or for a term otherwise ordered by the Court.

L. If the United States determines that the divestiture trustee is not acting diligently or in a reasonably cost-effective manner, the United States may recommend that the Court appoint a substitute divestiture trustee.

VII. Notice of Proposed Divestiture

A. Within two business days following execution of a definitive agreement to sell the Athenos Divestiture Assets to an Acquirer other than Emmi Roth or execution of a definitive agreement to sell the Polly-O Divestiture Assets to an Acquirer other than BelGioioso, Defendants or the divestiture trustee, whichever is then responsible for effecting the divestiture, must notify the United States of the proposed divestiture. If the divestiture trustee is responsible for completing the divestiture, the divestiture trustee also must notify Defendants. The notice must set forth the details of the proposed divestiture and list the name, address, and telephone number of each person not previously identified who offered or expressed an interest in or desire to acquire any ownership interest in the relevant Divestiture Assets.

B. Within 15 calendar days of receipt by the United States of a notice required by Paragraph VII.A, the United States may request from Defendants, the proposed Acquirer, other third parties, or the divestiture trustee additional information concerning the proposed divestiture, the proposed Acquirer, and other prospective Acquirers. Defendants and the divestiture trustee must furnish the additional information requested within 15 calendar days of the receipt of the request unless the United States provides written agreement to a different period.

C. Within 45 calendar days after receipt of a notice required by Paragraph VII.A or within 20 calendar days after the United States has been provided the additional information requested pursuant to Paragraph VII.B, whichever is later, the United States will provide written notice to Defendants and any divestiture trustee that states whether the United States, in its sole discretion, objects to the proposed Acquirer or any other aspect of the proposed divestiture. Without written notice that the United States does not object, a divestiture may not be consummated. If the United States provides written notice that it does not object, the divestiture may be consummated, subject only to Defendants' limited right to object to the sale under Paragraph VI.C of this Final Judgment. Upon objection by Defendants pursuant to Paragraph VI.C, a divestiture by the divestiture trustee may not be consummated unless approved by the Court.

D. No information or documents obtained pursuant to this Section may be divulged by the United States to any person other than an authorized representative of the executive branch of the United States, except in the course of legal proceedings to which the United States is a party, including grand jury proceedings, for the purpose of evaluating a proposed Acquirer or securing compliance with this Final Judgment, or as otherwise required by law.

E. In the event of a request by a third party for disclosure of information under the Freedom of Information Act, 5 U.S.C. 552, the United States Department of Justice's Antitrust Division will act in accordance with that statute, and the Department of Justice regulations at 28 CFR part 16, including the provision on confidential commercial information, at 28 CFR 16.7. Persons submitting information to the Antitrust Division should designate the confidential commercial information portions of all applicable documents and information under 28 CFR 16.7. Designations of confidentiality expire 10 years after submission, ''unless the submitter requests and provides justification for a longer designation period.'' *See* 28 CFR 16.7(b).

F. If at the time that a person furnishes information or documents to the United States pursuant to this Section, that person represents and identifies in writing information or documents for which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and marks each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure,'' the United States must give that person 10 calendar days' notice before divulging the material in any legal proceeding (other than a grand jury proceeding).

VIII. Financing

Defendants may not finance all or any part of any Acquirer's purchase of all or part of the Divestiture Assets.

IX. Asset Preservation and Hold Separate

Defendants must take all steps necessary to comply with the Asset Preservation and Hold Separate Stipulation and Order entered by the Court.

X. Affidavits

A. Within 20 calendar days of the filing of the Complaint in this matter, and every 30 calendar days thereafter until the divestitures required by this Final Judgment have been completed, each Defendant must deliver to the United States an affidavit, signed by (a) on behalf of Kraft Heinz, the Global Chief Financial Officer, and the Global General Counsel, and (b) on behalf of Lactalis, the Chief Financial Officer of LAG Holding, and the Chief Legal Officer of LAG Holding, describing in reasonable detail the fact and manner of that Defendant's compliance with this Final Judgment. The United States, in its sole discretion, may approve different signatories for the affidavits.

B. In the event Defendants are attempting to divest the Athenos Divestiture Assets to an Acquirer other than Emmi Roth or the Polly-O Divestiture Assets to an Acquirer other than BelGioioso, each affidavit required by Paragraph X.A must include: (1) The name, address, and telephone number of each person who, during the preceding 30 calendar days, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, an interest in the Divestiture Assets and describe in detail each contact with such persons during that period; (2) a description of the efforts Defendants have taken to solicit buyers for and complete the sale of the Divestiture Assets and to provide required information to prospective Acquirers; and (3) a description of any limitations placed by Defendants on information provided to prospective Acquirers. Objection by the United States to information provided by Defendants to prospective Acquirers must be made within 14 calendar days of receipt of the affidavit, except that the United States may object at any time if the information set forth in the affidavit is not true or complete.

C. Defendants must keep all records of any efforts made to divest the Athenos Divestiture Assets until one year after the Athenos Divestiture Assets are divested. Defendants must keep all records of any efforts made to divest the Polly-O Divestiture Assets until one year after the Polly-O Divestiture Assets are divested.

D. Within 20 calendar days of the filing of the Complaint in this matter, each Defendant must deliver to the United States an affidavit signed by (a) on behalf of Kraft Heinz, the Global Chief Financial Officer, and the Global General Counsel, and (b) on behalf of Lactalis, the Chief Financial Officer of

LAG Holding, and the Chief Legal Officer of LAG Holding, that describes in reasonable detail all actions that Defendant has taken and all steps that Defendant has implemented on an ongoing basis to comply with Section IX of this Final Judgment. The United States, in its sole discretion, may approve different signatories for the affidavits.

E. If a Defendant makes any changes to actions and steps described in affidavits provided pursuant to Paragraph X.D, the Defendant must, within 15 calendar days after any change is implemented, deliver to the United States an affidavit describing those changes.

F. Defendants must keep all records of any efforts made to comply with Section IX until the later of one year after the Athenos Divestiture Assets are divested or one year after the Polly-O Divestiture Assets are divested.

XI. Compliance Inspection

A. For the purposes of determining or securing compliance with this Final Judgment or of related orders such as the Asset Preservation and Hold Separate Stipulation and Order or of determining whether this Final Judgment should be modified or vacated, upon written request of an authorized representative of the Assistant Attorney General for the Antitrust Division, and reasonable notice to Defendants, Defendants must permit, from time to time and subject to legally recognized privileges, authorized representatives, including agents retained by the United States:

1. To have access during Defendants' office hours to inspect and copy, or at the option of the United States, to require Defendants to provide electronic copies of all books, ledgers, accounts, records, data, and documents in the possession, custody, or control of Defendants relating to any matters contained in this Final Judgment; and

2. to interview, either informally or on the record, Defendants' officers, employees, or agents, who may have their individual counsel present, relating to any matters contained in this Final Judgment. The interviews must be subject to the reasonable convenience of the interviewee and without restraint or interference by Defendants.

B. Upon the written request of an authorized representative of the Assistant Attorney General for the Antitrust Division, Defendants must submit written reports or respond to written interrogatories, under oath if requested, relating to any matters contained in this Final Judgment.

C. No information or documents obtained pursuant to this Section may be divulged by the United States to any person other than an authorized representative of the executive branch of the United States, except in the course of legal proceedings to which the United States is a party, including grand jury proceedings, for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

D. In the event of a request by a third party for disclosure of information under the Freedom of Information Act, 5 U.S.C. 552, the Antitrust Division will act in accordance with that statute, and the Department of Justice regulations at 28 CFR part 16, including the provision on confidential commercial information, at 28 CFR 16.7. Defendants submitting information to the Antitrust Division should designate the confidential commercial information portions of all applicable documents and information under 28 CFR 16.7. Designations of confidentiality expire 10 years after submission, ''unless the submitter requests and provides justification for a longer designation period.'' *See* 28 CFR 16.7(b).

E. If at the time that Defendants furnish information or documents to the United States pursuant to this Section, Defendants represent and identify in writing information or documents for which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and Defendants mark each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure,'' the United States must give Defendants 10 calendar days' notice before divulging the material in any legal proceeding (other than a grand jury proceeding).

XII. Notification

A. Unless a transaction is otherwise subject to the reporting and waiting period requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, 15 U.S.C. 18a (the ''HSR Act''), Lactalis may not, without first providing at least 30 calendar days advance notification to the United States, directly or indirectly acquire any assets of or any interest, including a financial, security, loan, equity, or management interest, in an entity involved in the sale of ricotta cheese to retailers in the United States during the term of this Final Judgment.

B. Lactalis must provide the notification required by this Section in the same format as, and in accordance with the instructions relating to, the Notification and Report Form set forth in the appendix to part 803 of title 16 of the Code of Federal Regulations, as amended, except that the information requested in Items 5 through 8 of the instructions must be provided only about the sale of ricotta cheese to retailers in the United States.

C. Notification must be provided at least 30 calendar days before acquiring any assets or interest and must include, beyond the information required by the instructions, the names of the principal representatives who negotiated the transaction on behalf of each party, and all management or strategic plans discussing the proposed transaction. If, within the 30 calendar days following notification, representatives of the United States make a written request for additional information, Defendants may not consummate the proposed transaction until 30 calendar days after submitting all requested information.

D. Early termination of the waiting periods set forth in this Section may be requested and, where appropriate, granted in the same manner as is applicable under the requirements and provisions of the HSR Act and rules promulgated thereunder. This Section must be broadly construed, and any ambiguity or uncertainty relating to whether to file a notice under this Section must be resolved in favor of filing notice.

XIII. No Reacquisition

Defendants may not reacquire any part of or any interest in the Divestiture Assets during the term of this Final Judgment without prior authorization of the United States.

XIV. Retention of Jurisdiction

The Court retains jurisdiction to enable any party to this Final Judgment to apply to the Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

XV. Enforcement of Final Judgment

A. The United States retains and reserves all rights to enforce the provisions of this Final Judgment, including the right to seek an order of contempt from the Court. Defendants agree that in a civil contempt action, a motion to show cause, or a similar action brought by the United States relating to an alleged violation of this Final Judgment, the United States may establish a violation of this Final Judgment and the appropriateness of a remedy therefor by a preponderance of the evidence, and Defendants waive any

argument that a different standard of proof should apply.

B. This Final Judgment should be interpreted to give full effect to the procompetitive purposes of the antitrust laws and to restore the competition the United States alleges was harmed by the challenged conduct. Defendants agree that they may be held in contempt of, and that the Court may enforce, any provision of this Final Judgment that, as interpreted by the Court in light of these procompetitive principles and applying ordinary tools of interpretation, is stated specifically and in reasonable detail, whether or not it is clear and unambiguous on its face. In any such interpretation, the terms of this Final Judgment should not be construed against either party as the drafter.

C. In an enforcement proceeding in which the Court finds that Defendants have violated this Final Judgment, the United States may apply to the Court for an extension of this Final Judgment, together with other relief that may be appropriate. In connection with a successful effort by the United States to enforce this Final Judgment against a Defendant, whether litigated or resolved before litigation, that Defendant agrees to reimburse the United States for the fees and expenses of its attorneys, as well as all other costs including experts' fees, incurred in connection with that effort to enforce this Final Judgment, including in the investigation of the potential violation.

D. For a period of four years following the expiration of this Final Judgment, if the United States has evidence that a Defendant violated this Final Judgment before it expired, the United States may file an action against that Defendant in this Court requesting that the Court order: (1) Defendant to comply with the terms of this Final Judgment for an additional term of at least four years following the filing of the enforcement action; (2) all appropriate contempt remedies; (3) additional relief needed to ensure the Defendant complies with the terms of this Final Judgment; and (4) fees or expenses as called for by this Section.

XVI. Expiration of Final Judgment

Unless the Court grants an extension, this Final Judgment will expire 10 years from the date of its entry, except that after five years from the date of its entry, this Final Judgment may be terminated upon notice by the United States to the Court and Defendants that the divestitures have been completed and continuation of this Final Judgment is no longer necessary or in the public interest.

XVII. Public Interest Determination

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16, including by making available to the public copies of this Final Judgment and the Competitive Impact Statement, public comments thereon, and any response to comments by the United States. Based upon the record before the Court, which includes the Competitive Impact Statement and, if applicable, any comments and response to comments filed with the Court, entry of this Final Judgment is in the public interest.

Date: _____

[Court approval subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C. 16]

_____

United States District Judge

United States District Court for the District of Columbia

United States of America, Plaintiff, v. *B.S.A. S.A., LAG Holding, Inc.,* and *The Kraft Heinz Company,* Defendants.

Civil Action No.: 1:21-cv-02976–RBW

Competitive Impact Statement

In accordance with the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h) (the ''APPA'' or ''Tunney Act''), the United States of America files this Competitive Impact Statement related to the proposed Final Judgment filed in this civil antitrust proceeding.

I. Nature and Purpose of the Proceeding

On September 15, 2020, B.S.A. S.A. (collectively with its subsidiaries LAG Holding, Inc., and Lactalis American Group, Inc., ''Lactalis'') agreed to acquire the natural cheese business of The Kraft Heinz Company (''Kraft Heinz'') in the United States, along with its grated cheese business in Canada and its entire cheese business outside North America, for approximately $3.2 billion. The United States filed a civil antitrust Complaint on November 10, 2021, seeking to enjoin the transaction. *See* Dkt. No. 1. The Complaint alleges that the likely effect of this transaction would be to substantially lessen competition for the sale of feta cheese to retailers in the United States and ricotta cheese to retailers in the metropolitan and surrounding area of New York, New York and in four metropolitan and surrounding areas in Florida in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

At the same time the Complaint was filed, the United States filed an Asset Preservation and Hold Separate Stipulation and Order (''Stipulation and Order'') and a proposed Final Judgment, which are designed to remedy the loss of competition alleged in the Complaint. *See* Dkt. Nos. 2–1 and 2–2.

Under the proposed Final Judgment, explained more fully below, Defendants are required to divest Kraft Heinz's entire Athenos and Polly-O businesses, including the brand names, all products sold under those brand names, and other assets related to or used in these businesses to Emmi Roth USA, Inc. and BelGioioso Cheese, Inc., respectively, or to alternative acquirers acceptable to the United States, within 30 calendar days after entry of the Stipulation and Order. These divestitures will protect competition by enabling the acquirers of the Athenos and Polly-O businesses to step into the shoes of Kraft Heinz and compete with Lactalis in the feta and ricotta markets.

Under the terms of the Stipulation and Order, Defendants must also take certain steps to operate, preserve, and maintain the full economic viability, marketability, and competitiveness of the Athenos Divestiture Assets and the Polly-O Divestiture Assets. In addition, Lactalis must hold entirely separate, distinct, and apart from its other operations, the management, sales, and operations of the Athenos Divestiture Assets and the Polly-O Divestiture Assets. The purpose of these terms in the Stipulation and Order is to ensure that competition is maintained while the divestitures are being accomplished. The Court signed the Stipulation and Order on November 13, 2021, and entered the Stipulation and Order on November 15, 2021. *See* Dkt. No. 3.

The United States and Defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA. Entry of the proposed Final Judgment by the Court will terminate this action, except that the Court will retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof.

II. Description of Events Giving Rise to the Alleged Violations

A. The Defendants and the Transaction

B.S.A. S.A. is a French company operating under the name Lactalis Group, organized and existing under the laws of France, with its headquarters in Laval, France. It is one of the largest dairy companies in the world, selling cheese in the United States through its subsidiaries, LAG Holding, Inc. and Lactalis American Group, Inc. LAG Holding, Inc., a Delaware corporation with its headquarters in Buffalo, New

York, and Lactalis American Group, Inc. generated natural cheese sales of approximately $429 million at retail outlets in the United States in 2020. In the United States, Lactalis sells natural cheeses primarily under the Galbani and Président brand names.

Kraft Heinz is a Delaware corporation co-headquartered in Pittsburgh, Pennsylvania and Chicago, Illinois. Kraft Heinz is one of the largest food products and beverage companies in the world. It is the largest supplier of natural cheeses to grocery stores and other retail outlets in the United States, with retail sales of its natural cheeses totaling over $2.2 billion in 2020. Kraft Heinz sells natural cheeses primarily under the Kraft, Cracker Barrel, Athenos, and Polly-O brand names.

Pursuant to a September 15, 2020 asset purchase agreement, Lactalis will acquire for approximately $3.2 billion Kraft Heinz's interests in its: (1) Natural cheese business in the United States, which includes feta, ricotta, and many other types of cheeses; (2) grated cheese business in Canada; and (3) entire cheese business outside North America (the ''Transaction''). Kraft Heinz is retaining a significant portion of its cheese business in the United States, consisting of its processed cheese and cream cheese businesses, marketed under the Kraft Singles, Velveeta, Cheez Whiz, and Philadelphia Cream Cheese brand names.

B. The Competitive Effects of the Transaction

The Complaint alleges that the Transaction will result in anticompetitive effects in the markets for the sale of feta cheese to retailers in the United States and the sale of ricotta cheese to retailers in the metropolitan and surrounding area of New York, New York (the ''New York Metro Market'') and in four metropolitan and surrounding areas in Florida: Miami/Ft. Lauderdale, Tampa/St. Petersburg, Orlando, and Jacksonville (collectively, the ''Florida Metro Markets'').

Cheeses are sold to retailers (such as grocery stores, supermarkets, mass merchandisers like Wal-Mart, and club stores like Sam's Club) as branded cheeses or private label cheeses. A branded cheese bears a brand name controlled by the cheese supplier (*e.g.,* Kraft Heinz's Athenos and Polly-O brands) and is usually carried by multiple retailers. A private label cheese is usually sold under a name owned by the retailer (*e.g.,* Wal-Mart's Great Value private label), and is typically offered only in that retailer's stores. Grocery stores and other food retailers act as proxies for individual customers and seek to offer a variety of products demanded by their customers. Accordingly, retailers strive to carry products and brands that their customers value, and may vary their offerings to meet local customer demand.

The Transaction would combine the two largest suppliers of feta cheese sold to retailers in the United States and the two largest suppliers of ricotta cheese sold to retailers in the New York Metro Market and in each of the Florida Metro Markets. As alleged in the Complaint, eliminating the head-to-head competition between Lactalis and Kraft Heinz would likely lead to higher prices, lower quality, and less innovation for these products for retailers (and consumers) in the relevant markets.

1. Relevant Product Markets

A typical starting point for merger analysis is defining a relevant market, which has both a product and a geographic dimension. Courts define relevant markets to help determine the areas of competition most likely to be affected by a merger.

a. Feta Cheese Sold to Retailers

As alleged in the Complaint, feta cheese sold to retailers is a relevant antitrust product market in which to analyze the effects of the Transaction. Feta cheese originated in Greece, and is primarily used as an ingredient in food dishes. There are no reasonable substitutes for feta cheese for most consumers. A hypothetical monopolist supplier of feta cheese to retailers likely would find it profitable to increase its prices by at least a small but significant non-transitory amount (*e.g.,* five percent). Consumers are unlikely to sufficiently reduce their purchases of feta cheese or shift to a different cheese or other products to render such a price increase unprofitable. Retailers, buying on behalf of consumers, are also unlikely to sufficiently reduce purchases of feta cheese to render such a price increase unprofitable. Accordingly, feta cheese sold to retailers is a relevant product market and line of commerce within the meaning of Section 7 of the Clayton Act, 15 U.S.C. 18.

Defining a market for feta cheese that is sold to retailers is also consistent with industry recognition and practice. As the Complaint indicates, suppliers of feta cheese to retailers typically (1) monitor the retail prices of competing feta cheeses and set their prices and promotional spending accordingly, (2) do not set the price they charge for feta cheese based on the prices of other cheeses or other consumer products, (3) track their sales to retailers separately from their sales to other distribution channels (*i.e.,* foodservice and the ingredients or industrial channels), (4) have sales employees dedicated to serving retailers, and (5) sell feta cheese to retailers in packaging and package sizes that are different than that used for feta cheese sold through other distribution channels. These factors further support that feta cheese sold to retailers is a relevant product market and line of commerce within the meaning of Section 7 of the Clayton Act, 15 U.S.C. 18.

b. Ricotta Cheese Sold to Retailers

As alleged in the Complaint, ricotta cheese sold to retailers is a relevant antitrust product market in which to analyze the effects of the Transaction. Ricotta is a soft cheese that originated in Italy, and is primarily used as an ingredient in food dishes. There are no reasonable substitutes for ricotta cheese for most consumers. A hypothetical monopolist supplier of ricotta cheese to retailers likely would find it profitable to increase its prices by at least a small but significant non-transitory amount (*e.g.,* five percent). Similar to feta cheese, consumers and retailers are unlikely to sufficiently reduce their purchases of ricotta cheese or shift to a different cheese or other products to render such a price increase unprofitable. In addition, defining a market for ricotta cheese that is sold to retailers is consistent with industry recognition and practice for the same reasons described above for feta cheese. Accordingly, ricotta cheese sold to retailers is a relevant product market and line of commerce within the meaning of Section 7 of the Clayton Act, 15 U.S.C. 18.

2. Relevant Geographic Markets

The relevant geographic markets for analyzing the effects of the Transaction on competition for feta and ricotta cheeses sold to retailers are best defined by reference to the locations of the retailers that purchase feta and ricotta cheeses in order to then sell those products to consumers. This approach to defining the relevant geographic markets is appropriate because suppliers of feta and ricotta cheeses to retailers assess the competitive conditions in particular localities, including local demand for feta and ricotta cheeses, as well as local demand for the suppliers' own brands as compared to competing brands and to private label offerings. As a result, suppliers of feta and ricotta cheeses can charge different prices, or offer different

levels of promotional funding, to retailers in different locations based on local competitive conditions. If targeted for a price increase or reduction in promotional funding, retailers in a given locality would likely not be able to render such conduct unprofitable by purchasing feta or ricotta cheeses outside of the relevant geography and transporting it to their retail locations.

As the Complaint alleges, where feta and ricotta cheese suppliers can successfully vary prices and promotional funding based on retailer customer location, the goal of geographic market definition is to identify the area encompassing the location of potentially targeted customers. The relevant geographic markets described below encompass the locations of retailers that would likely be targeted by suppliers for price increases as a result of the Transaction.

a. The Relevant Geographic Markets for Feta Cheese Sold to Retailers

The relevant geographic market for the sale of feta cheese to retailers may be defined as narrowly as individual metropolitan and surrounding areas. A hypothetical monopolist supplier of feta cheese to retailers in any given metropolitan and surrounding area in the United States likely would find it profitable to increase its prices by at least a small but significant and non-transitory amount (*e.g.,* five percent). Therefore, each metropolitan and surrounding area in the United States is a relevant geographic market and section of the country within the meaning of Section 7 of the Clayton Act, 15 U.S.C. 18.

As the Complaint alleges, in circumstances where competitive conditions are similar, it is appropriate to aggregate local markets into a larger relevant market for analytical convenience. The competitive conditions across the country are similar for the sale of feta cheese to retailers. Kraft Heinz's Athenos feta and Lactalis's Président feta are the two top-selling feta cheese brands in the United States. While some regional brands of feta cheese exist, none place a significant competitive constraint on Defendants in any particular metropolitan and surrounding area. Therefore, it is appropriate to analyze competition for the sale of feta cheese to retailers on a national basis.

b. The Relevant Geographic Markets for Ricotta Cheese Sold to Retailers

The relevant geographic markets for the sale of ricotta cheese to retailers are the New York Metro Market and each of the Florida Metro Markets. In each of these markets, Defendants compete vigorously with each other for sales of ricotta cheese to retailers. A hypothetical monopolist supplier of ricotta cheese to retailers in the New York Metro Market and in each of the Florida Metro Markets likely would increase its price by at least a small but significant and non-transitory amount (*e.g.,* five percent). Therefore, the New York Metro Market and each of the Florida Metro Markets are relevant geographic markets and sections of the country within the meaning of Section 7 of the Clayton Act, 15 U.S.C. 18.

3. The Transaction Would Result in Large Combined Market Shares and Likely Substantially Lessen Head-To-Head Competition Between Two Particularly Close Competitors

The Transaction would combine Lactalis and Kraft Heinz, the two largest suppliers of feta cheese to retailers nationally, and the two largest suppliers of ricotta cheese to retailers in the New York Metro Market and in each of the Florida Metro Markets, resulting in a substantial increase in concentration in these markets.

The Supreme Court has held that mergers that significantly increase concentration in already concentrated markets are presumptively anticompetitive and therefore presumptively unlawful. To measure market concentration, courts often use the Herfindahl-Hirschman Index (''HHI'') as described in the *U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines*. HHIs range from 0 in markets with no concentration to 10,000 in markets where one firm has a 100% market share. According to the *Horizontal Merger Guidelines,* mergers that increase the HHI by more than 200 and result in an HHI above 2,500 in any market are presumed to be anticompetitive and, therefore, unlawful.

The Complaint alleges that the Transaction is presumptively unlawful for the sale of feta cheese to retailers nationally. Defendants are the two largest suppliers of feta cheese to retailers in the United States, and their Athenos and Président feta cheese brands combined would account for approximately 65% of all feta cheese sales by retailers nationally. In a national market for feta cheese sold by retailers, the Transaction would increase the HHI by more than 2,100 points, resulting in a highly concentrated market with a post-acquisition HHI of more than 4,300 points. Thus, the Transaction is presumptively unlawful for the sale of feta cheese to retailers nationally.

As alleged in the Complaint, the Transaction is also presumptively unlawful for the sale of ricotta cheese to retailers in the New York Metro Market and in each of the Florida Metro Markets. In each of these markets, the Defendants are the two largest suppliers of ricotta cheese to retailers. In the New York Metro Market, their Polly-O and Galbani ricotta cheese brands combined would account for approximately 70% of all ricotta cheese sales by retailers, and the Transaction would increase the HHI by more than 2,400 points, resulting in a highly concentrated market with a post-acquisition HHI of more than 5,000 points. In each of the Florida Metro Markets, the Defendants' Polly-O and Galbani ricotta cheese brands combined would account for over 65% of all ricotta cheese sales by retailers, and the Transaction would increase the HHI by more than 1,500 points, resulting in highly concentrated markets, each with a post-acquisition HHI of more than 4,400 points. Thus, the Transaction is presumptively unlawful in the New York Metro Market and in each of the Florida Metro Markets.

The Complaint further alleges that Lactalis and Kraft Heinz are particularly close competitors for feta cheese sold to retailers nationally, and for ricotta cheese sold to retailers in the New York Metro Market and in each of the Florida Metro Markets. The Defendants are the only two major brands for feta and ricotta cheese in the relevant geographic markets and compete aggressively with each other on pricing and promotions. The Defendants also compete to offer new and innovative products and features, such as Kraft Heinz's flip top container for Athenos crumbled feta cheese and Lactalis's double cream ricotta cheese. Accordingly, the proposed combination of Lactalis and Kraft Heinz would likely lead to higher prices, lower quality, and less innovation for feta cheese sold to retailers nationally and for ricotta cheese sold to retailers in the New York Metro Market and in each of the Florida Metro Markets.

4. Difficulty of Entry or Expansion

As alleged in the Complaint, new entry and expansion by competitors will likely neither be timely nor sufficient in scope to prevent the likely anticompetitive effects of the Transaction. Barriers to entry and expansion are high and include the substantial time and expense required to build a brand's reputation and overcome existing consumer preferences through

promotional and advertising activity as well as the substantial sunk costs needed to secure the distribution and placement of a new entrant's products in retail outlets (*e.g.,* paying slotting fees to obtain shelf space at supermarkets and other food retailers).

The Complaint also alleges that the likely anticompetitive effects of the Transaction are not likely to be reversed or outweighed by any efficiencies that the Transaction may achieve.

III. Explanation of the Proposed Final Judgment

To remedy the likely anticompetitive effects of the Transaction, the United States required the Defendants to divest Kraft Heinz's competing feta cheese business (the Athenos Divestiture Business), and its competing ricotta cheese business (the Polly-O Divestiture Business) to acquirers who will step into the shoes of Kraft Heinz and preserve the competition with Lactalis in the relevant geographic markets. Thus, the relief required by the proposed Final Judgment will remedy the loss of competition alleged in the Complaint by establishing independent and economically viable competitors in the markets for the sale of feta cheese nationally and for the sale of ricotta cheese in the New York Metro Market and in each of the Florida Metro Markets.

A. Athenos Divestiture Provisions

Paragraph IV.A of the proposed Final Judgment requires Defendants, within 30 days after the entry of the Stipulation and Order by the Court, to divest the Athenos Divestiture Assets to Emmi Roth USA, Inc. (''Emmi Roth'') or an alternative acquirer acceptable to the United States, in its sole discretion. Emmi Roth is an established cheese producer based in Fitchburg, Wisconsin. With the divestiture of Kraft Heinz's Athenos business, Emmi Roth, or an alternative qualified acquirer, will be able to enter or expand feta cheese sales to grocery stores and other retailers across the United States. The United States, in its sole discretion, may agree to one or more extensions of the time period to complete the divestiture of the Athenos Divestiture Assets, not to exceed 60 calendar days in total, and will notify the Court of any extensions. Paragraph IV.C of the proposed Final Judgment requires that the divestiture must include the entire Athenos Divestiture Assets and that the assets must be divested in such a way as to satisfy the United States, in its sole discretion, that the assets can and will be operated by the acquirer as a viable, ongoing business that can compete effectively in the sale of feta cheese to retailers. Defendants must take all reasonable steps necessary to accomplish the divestitures quickly and must cooperate with any acquirer.

The Athenos Divestiture Assets are defined in Paragraph II.E of the proposed Final Judgment as all rights, titles, and interests in and to all tangible and intangible property and assets relating to or used in connection with the Athenos Divestiture Business.[1] These assets include: (1) The Athenos Brand Name,[2] including the exclusive right to the name in all sales channels (including the retail, foodservice, and ingredients or industrial channels), and all other intellectual property owned, licensed, or sublicensed, including patents, patent applications, and inventions or discoveries that may be patentable, registered and unregistered copyrights and copyright applications, and registered and unregistered trademarks, trade dress, service marks, trade names, and trademark applications; (2) all contracts, contractual rights, and customer relationships, and all other agreements, commitments, and understandings, including agreements with suppliers, manufacturers, co-packers, and retailers, teaming agreements, leases, and all outstanding offers or solicitations to enter into a similar arrangement; (3) all licenses, permits, certifications, approvals, consents, registrations, waivers, and authorizations, and all pending applications or renewals; (4) all records and data, including customer lists, accounts, sales, and credit records; production, repair, maintenance, and performance records; manuals and technical information Defendants provide to their own employees, customers, suppliers, agents, or licensees; records and research data concerning historic and current research and development activities; and drawings, blueprints, and designs; and (5) all other intangible property, including commercial names and d/b/a names, technical information such as recipes and formulas, computer software and related documentation, know-how, trade secrets, design protocols, specifications for materials, parts, and devices, procedures for safety, quality assurance, and control, design tools and simulation capabilities, and rights in internet websites and domain names.

Importantly, the Athenos Divestiture Assets include all rights to the Athenos Brand Name, which is currently used to sell feta, gorgonzola, blue cheese, hummus, and pita chips. By requiring the full divestiture of the Athenos Brand Name, which will allow the acquirer to use the Athenos Brand Name for more than just feta, the proposed Final Judgment will enable the acquirer to more effectively compete in the sale of feta cheese by (1) avoiding the potential consumer confusion and potential harm to the Athenos Brand Name that could result from having both the acquirer and Lactalis marketing and selling Athenos-branded products, and (2) by giving the acquirer control over the sale of all Athenos Products in all three channels of distribution—retail, foodservice, and ingredients or industrial.[3] In this case, it is appropriate to require a divestiture that is broader than the harm alleged in the Complaint in order to preserve competition. *See, e.g., Merger Remedies Manual,* Antitrust Division, September 2020, at 9 (explaining that the Division ''may seek to include a full line of products in the divestiture package, even when the antitrust concern relates to only a subset of those products''). The divestiture of the entire Athenos Brand Name (and the entire Athenos Divestiture Business) will allow the divestiture buyer the opportunity to use the divested brand in the same way that Kraft Heinz uses it to compete today.

In addition to the Athenos Divestiture Assets, at a later date, the acquirer will acquire additional physical assets and contracts relating to Athenos feta cheese. These additional assets are referred to as Athenos Transitional Manufacturing Assets in Paragraph II.I of the proposed Final Judgment and defined as: (1) Production lines numbers 25 and 26 that are used by the Athenos Divestiture Business for crumbling and packaging feta cheese and are located at Kraft Heinz's facility in Wausau, Wisconsin; (2) the feta cheese packaging mold used to produce plastic feta lids and containers that was purchased by Kraft Heinz in 2021 and is located at the facilities of packaging supplier RPC Bramlage-WIKO USA, Inc. in

[1] The Athenos Divestiture Business is defined in Paragraph II.F of the proposed Final Judgment as ''the worldwide business of the sale of Athenos Products by Kraft Heinz.'' Athenos Products is defined in Paragraph II.H of the proposed Final Judgment as ''any product that Kraft Heinz sold, sells, or has plans to sell under the Athenos Brand Name anywhere in the world.''

[2] The Athenos Brand Name is defined in Paragraph II.D of the proposed Final Judgment as ''Athenos and any other name that uses, incorporates, or references the Athenos name.''

[3] The retail channel is comprised of grocery stores, supermarkets, mass merchandisers like Wal-Mart, and club stores like Sam's Club; the foodservice channel is for distributors that sell to restaurants, cafeterias, hospitals, and other businesses that prepare and serve food; and the ingredients/industrial channel is for companies that primarily prepare and package the frozen entrées that are sold in grocery stores and supermarkets.

Morgantown, Pennsylvania; and (3) contracts and agreements between Kraft Heinz and Agropur, J. Rettenmaier USA LP, International Paper Company, Berry Global, Inc., Weber Packaging Solutions, Inc., and Bramlage, Inc.

Because the Athenos Transitional Manufacturing Assets will be used by Defendants to fulfill their obligations under the supply contract permitted by Paragraph IV.M of the proposed Final Judgment, Lactalis is permitted, pursuant to Paragraph IV.N of the proposed Final Judgment, to retain these Athenos Transitional Manufacturing Assets until the supply agreement expires or is terminated. At that point, Defendants are required to sell and transfer to the acquirer of the Athenos Divestiture Assets the Athenos Transitional Manufacturing Assets within 60 days. This is preferable because Lactalis will be responsible for the maintenance and upkeep of the Athenos Transitional Manufacturing Assets for the duration of any supply contract, and pursuant to Paragraph IV.O of the proposed Final Judgment, Lactalis is required to warrant that the Athenos Transitional Manufacturing Assets are operational and without material defect at the time of such transfer to the acquirer.

Similarly, Paragraph IV.K of the proposed Final Judgment provides the acquirer of the Athenos Divestiture Assets with the option to have a series of third-party contracts relating to the production of Athenos Products assigned to it at any time prior to the conclusion of any transition services agreement entered into between the acquirer and Defendants pursuant to Paragraph IV.P of the proposed Final Judgment. These third-party contracts are referred to as the Athenos Transitional Service Contracts in the proposed Final Judgment and are defined in Paragraph II.J as contracts between Kraft Heinz and Prairie Farms, Great Lake Cheese Company, Inc., Marathon Cheese Corporation, Cedar's Mediterranean Foods, Inc., and Saputo Cheese USA, Inc. An acquirer, such as Emmi Roth, that is already a cheese producer with an existing series of suppliers and contracts may prefer not to have some or even any of the Athenos Transitional Services Contracts assigned to it pursuant to Paragraph IV.K of the proposed Final Judgment, but, for a different acquirer, this option will ensure continuity in supply while also allowing that acquirer to evaluate its needs.

The proposed Final Judgment also contains provisions intended to facilitate the acquirer's efforts to hire employees whose job responsibilities relate to the Athenos Divestiture Assets, enabling the acquirer to successfully operate the Athenos business. Paragraph IV.H of the proposed Final Judgment requires Defendants to provide the acquirer and the United States with organization charts and information relating to these employees and to make them available for interviews with the acquirer. It also prohibits Defendants from interfering with any negotiations by the acquirer to hire these employees. In addition, for employees who elect employment with the acquirer, Defendants must waive all non-compete and non-disclosure agreements; vest and pay on a prorated basis any bonuses, incentives, other salary, benefits, or other compensation fully or partially accrued at the time of transfer; vest any unvested pension and other equity rights; and provide all other benefits that the employees would generally be provided had those employees continued employment with Defendants, including any retention bonuses or payments. Finally, the timeline for when these employees may be hired by the acquirer has been set to ensure that employees providing any transition services pursuant to a transition services agreement entered into pursuant to Paragraph IV.P of the proposed Final Judgment are not interrupted.

Paragraph IV.H of the proposed Final Judgment further provides that Defendants may not directly solicit to rehire any Athenos-related employees who were hired by the acquirer, unless an employee is terminated or laid off by the acquirer or the acquirer agrees in writing that Defendants may solicit to rehire that individual. This non-solicitation period runs for 12 months from the date of the divestiture. This provision serves two purposes. First, it promotes a period of stability that will aid the acquirer in assuming control of the Athenos business. Second, many food retailers conduct periodic category reviews in which they evaluate their brand offerings and shelf space allocations, and a one-year non-solicitation period will permit the acquirer to complete at least one such category review at most food retailers. It is important to note, however, that this non-solicitation provision does not prohibit Defendants from advertising employment openings using general solicitations or advertisements and rehiring anyone who applies for an opening through a general solicitation or advertisement.

The proposed Final Judgment contains several provisions to facilitate the transition of the Athenos Divestiture Business to the acquirer. First, Paragraph IV.J of the proposed Final Judgment will facilitate the transfer to the acquirer of customer and other contractual relationships that are included within the Athenos Divestiture Assets. Defendants must transfer all contracts, agreements, and customer relationships (or portions of such contracts, agreements, and customer relationships), including all supply and sales contracts and co-packing and packaging supplier agreements, to the acquirer and must use best efforts to assign, subcontract, or otherwise transfer contracts or agreements that require the consent of another party before assignment, subcontracting, or otherwise transferring. Defendants must not interfere with any negotiations between the acquirer of the Athenos Divestiture Assets and a contracting party. These protections also apply to any of the Athenos Transitional Services Contracts that the acquirer can elect to have assigned under Paragraph IV.K of the proposed Final Judgment.

Second, Paragraph IV.M of the proposed Final Judgment requires Defendants, at the acquirer's option, to enter into a supply contract or contracts for the processing and packaging of Athenos Products sufficient to meet the acquirer's needs for a period of up to two years on terms and conditions reasonably related to market conditions for the processing and packaging of Athenos Products. A two-year term is appropriate here to permit the acquirer to move the physical equipment included in the Athenos Transitional Manufacturing Assets to a facility that will allow for the most efficient operation of the Athenos Divestiture Business. Supply contracts of this nature are common in this industry; indeed, Kraft Heinz today outsources much of its cheese production to other cheese manufacturers, including its feta cheese production. Companies operating in this industry have experience negotiating and managing these types of supply contracts, and such arrangements are used by other natural cheese brands. In addition, Paragraph IV.M of the proposed Final Judgment prohibits employees of the Defendants tasked with providing services pursuant to any supply contract from sharing any competitively sensitive information of the acquirer with any other employee of Defendants.

The acquirer may terminate any supply contract described in Paragraph IV.M of the proposed Final Judgment, or any portion of any such supply contract, without cost or penalty at any time upon commercially reasonable written notice. The United States, in its sole discretion, may approve one or more

extensions of any supply contract for up to an additional 12 months, and if the acquirer requests such an extension, Defendants must notify the United States in writing at least three months prior to the date the supply contract expires. Any amendments to or modifications of any provisions of a supply contract are subject to approval by the United States, in its sole discretion.

Finally, Paragraph IV.P of the proposed Final Judgment requires Defendants, at the acquirer's option and subject to approval by the United States in its sole discretion, to enter into a transition services agreement for a period of up to six months. Among other things, this transition services agreement will ensure that the acquirer has sufficient access to Athenos-related enterprise data and personnel that are knowledgeable about this data, so as to avoid disruption to the Athenos Divestiture Business while Defendants work to transfer this data to the acquirer and the acquirer interviews and makes offers of employment to Athenos personnel. The acquirer may terminate the transition services agreement, or any portion of it, without cost or penalty at any time upon commercially reasonable written notice. The United States, in its sole discretion, may approve one or more extensions of any transition services agreement for a total of up to an additional six months, and if the acquirer requests such an extension, Defendants must notify the United States in writing at least 30 days prior to the date the transition services agreement expires. Any amendments to or modifications of any provisions of a transition services agreement are also subject to approval by the United States, in its sole discretion. The employees of Defendants tasked with providing transition services must not share any competitively sensitive information of the acquirer of the Athenos Divestiture Assets with any other employee of Defendants.

B. Polly-O Divestiture Provisions

Paragraph V.A of the proposed Final Judgment requires Defendants, within 30 days after the entry of the Stipulation and Order by the Court, to divest the Polly-O Divestiture Assets to BelGioioso Cheese, Inc. (''BelGioioso'') or an alternative acquirer acceptable to the United States, in its sole discretion. BelGioioso is an established cheese producer based in Green Bay, Wisconsin. With the divestiture of Kraft Heinz's Polly-O business, BelGioioso, or an alternative qualified acquirer, will be able to enter or expand ricotta cheese sales to grocery stores and other retailers in New York and Florida. The United States, in its sole discretion, may agree to one or more extensions of the time period to complete the divestiture of the Polly-O Divestiture Assets, not to exceed 60 calendar days in total, and will notify the Court of any extensions. Paragraph V.C of the proposed Final Judgment requires that the Polly-O Divestiture Assets must be divested in such a way as to satisfy the United States, in its sole discretion, that the assets can and will be operated by the acquirer as a viable, ongoing business that can compete effectively in the sale of ricotta cheese to retailers. Defendants must take all reasonable steps necessary to accomplish the divestitures quickly and must cooperate with any acquirer.

The Polly-O Divestiture Assets are defined in Paragraph II.S of the proposed Final Judgment as all rights, titles, and interests in and to all intangible and tangible property and assets, relating to or used in connection with the Polly-O Divestiture Business.[4] These assets include: (1) The Polly-O Brand Name,[5] including the exclusive right to the name in all sales channels (including the retail, foodservice, and ingredients or industrial channels), and all other intellectual property owned, licensed, or sublicensed, including patents, patent applications, and inventions or discoveries that may be patentable, registered and unregistered copyrights and copyright applications, and registered and unregistered trademarks, trade dress, service marks, trade names, and trademark applications; (2) the Shared Recipes License, which is defined in Paragraph II.X of the proposed Final Judgment as a perpetual, royalty-free, paid-up, irrevocable, worldwide, non-exclusive license to the formulas, recipes and related trade secrets, know-how, confidential business information and related data that were used by Kraft Heinz for the production of cheese sold under both the Polly-O Brand Name and any other Kraft Heinz brand name; (3) all contracts, contractual rights, and customer relationships, and all other agreements, commitments, and understandings, including agreements with suppliers, manufacturers, co-packers, and retailers, teaming agreements, leases, and all outstanding offers or solicitations to enter into a similar arrangement; (4) all licenses, permits, certifications, approvals, consents, registrations, waivers, and authorizations, and all pending applications or renewals; (5) all records and data, including customer lists, accounts, sales, and credit records; production, repair, maintenance, and performance records; manuals and technical information Defendants provide to their own employees, customers, suppliers, agents, or licensees; records and research data concerning historic and current research and development activities; and drawings, blueprints, and designs; and (6) all other intangible property, including commercial names and d/b/a names, technical information, computer software and related documentation, know-how, trade secrets, design protocols, specifications for materials, parts, and devices, procedures for safety, quality assurance, and control, design tools and simulation capabilities, and rights in internet websites and domain names.

Similar to the Athenos Divestiture Assets, the proposed Final Judgment requires Defendants to divest all rights to the Polly-O Brand Name, which is currently used to sell ricotta, chunk mozzarella, shredded mozzarella, string mozzarella,[6] twist mozzarella-cheddar, fresh mozzarella, asiago, parmesan, romano, and Italian cheese blends. By requiring the full divestiture of the Polly-O Brand Name, the proposed Final Judgment will enable the acquirer to more effectively compete in the sale of ricotta cheese by (1) avoiding the potential consumer confusion and potential harm to the brand that could result from having both the acquirer and Lactalis marketing and selling Polly-O branded cheeses, and (2) by giving the acquirer control over the sale of all Polly-O Products in all three channels of distribution—retail, foodservice and ingredients or industrial. For the same reasons described with respect to the Athenos divestiture provisions, requiring Defendants to divest the full Polly-O Brand Name will preserve competition. Most notably, with respect to the Polly-O Brand Name, it will permit the acquirer to offer both ricotta and chunk mozzarella cheese under the same brand name, which is important for competing in the market for the sale

[4] The Polly-O Divestiture Business is defined in Paragraph II.T of the proposed Final Judgment as ''the worldwide business of the sale of Polly-O Products by Kraft Heinz.'' Polly-O Products is defined in Paragraph II.W of the proposed Final Judgment as ''any product that Kraft Heinz sold, sells, or has plans to sell under the Polly-O Brand Name anywhere in the world.''

[5] The Polly-O Brand Name is defined in Paragraph II.R of the proposed Final Judgment as ''Polly-O and any other name that uses, incorporates, or references the Polly-O name.''

[6] Both Defendants also sell mozzarella string cheese in many local areas, particularly in the eastern United States. However, since the proposed Final Judgment requires divesting the entire Polly-O business—including mozzarella string cheese—it fully remedies any potential competitive harm to purchasers of mozzarella string cheese.

of ricotta cheese to retailers because both cheeses are often promoted in tandem.

Under the Shared Recipes License defined in Paragraph II.X of the proposed Final Judgment, the acquirer will also receive a perpetual, royalty free, paid-up, irrevocable, worldwide, non-exclusive license to the formulas, recipes and related trade secrets, know-how, confidential business information and related data that were used by Kraft Heinz for the production of cheese sold under both the Polly-O Brand Name and any other Kraft Heinz brand name. The Shared Recipes License will enable the acquirer to produce and sell Polly-O cheeses that share recipes with any other Kraft Heinz product.

Paragraph V.H of the proposed Final Judgment also contains provisions intended to facilitate the acquirer's efforts to hire employees whose job responsibilities relate in any way to the Polly-O Divestiture Assets. These provisions are the same as those applicable to employees whose job responsibilities relate in any way to the Athenos Divestiture Assets, as described above. Specifically, Paragraph V.H of the proposed Final Judgment requires Defendants to provide the acquirer and the United States with organization charts and information relating to these employees and to make them available for interviews with the acquirer. It also prohibits Defendants from interfering with any negotiations by the acquirer to hire these employees. In addition, for employees who elect employment with the acquirer, Defendants must waive all non-compete and non-disclosure agreements; vest and pay on a prorated basis any bonuses, incentives, other salary, benefits, or other compensation fully or partially accrued at the time of transfer; vest any unvested pension and other equity rights; and provide all other benefits that the employees would generally be provided had those employees continued employment with Defendants, including any retention bonuses or payments. Finally, the timeline for when these employees may be hired by the acquirer has been set to ensure that employees providing any transition services pursuant to a transition services agreement entered into pursuant to Paragraph V.N of the proposed Final Judgment are not interrupted.

Paragraph V.H of the proposed Final Judgment further provides that Defendants may not directly solicit to rehire any Polly-O-related employees who were hired by the acquirer, unless an employee is terminated or laid off by the acquirer or the acquirer agrees in writing that Defendants may solicit to rehire that individual. This non-solicitation period runs for 12 months from the date of the divestiture. This provision serves two purposes. First, it promotes a period of stability that will aid the acquirer in assuming control of the Athenos business. Second, many food retailers conduct periodic category reviews in which they evaluate their brand offerings and shelf space allocations, so a one-year non-solicitation period permits the acquirer to complete at least one such category review at most food retailers. It is important to note, however, that this non-solicitation provision does not prohibit Defendants from advertising employment openings using general solicitations or advertisements and rehiring anyone who applies for an opening through a general solicitation or advertisement.

Paragraph II.U of the proposed Final Judgment defines Polly-O Excluded Contracts. These are contracts that BelGioioso has informed Defendants that it does not want included as part of the Polly-O Divestiture Assets. The Polly-O Excluded Contracts are contracts and agreements between Kraft Heinz and Foremost Farms USA Cooperative, Marathon Cheese Corporation, Saputo Cheese USA Inc., Amcor Flexibles North America, Inc., International Paper Company, Berry Global, Inc, Transcontinental US LLC, and J. Rettenmaier USA LP. As an established producer of cheese that has an existing series of suppliers and contracts, BelGioioso reviewed these contracts and determined that it did not need them in order to effectively operate the Polly-O Divestiture Business. To avoid saddling BelGioioso with unnecessary or potentially duplicative contracts, those contracts are excluded from the Polly-O Divestiture Assets. However, if Defendants divest the Polly-O Divestiture Assets to an acquirer other than BelGioioso, and that alternative acquirer determines it needs these Polly-O Excluded Contracts, Paragraph V.K of the proposed Final Judgment requires Defendants to assign, subcontract, or otherwise transfer any of the Polly-O Excluded Contracts to any such acquirer of the Polly-O Divestiture Assets.

As with the Athenos Divestiture Business, the proposed Final Judgment contains several provisions to facilitate the transition of the Polly-O Divestiture Business to the acquirer. First, Paragraph V.J of the proposed Final Judgment will facilitate the transfer to the acquirer of customer and other contractual relationships that are included within the Polly-O Divestiture Assets. As with the Athenos divestiture provisions above, Defendants must transfer all such contracts, agreements, and customer relationships (or portions of such contracts, agreements, and customer relationships), including all supply and sales contracts and co-packing and packaging supplier agreements, to the acquirer and must use best efforts to assign, subcontract, or otherwise transfer contracts or agreements that require the consent of another party before assignment, subcontracting, or otherwise transferring. Defendants must not interfere with any negotiations between the acquirer and a contracting party. These protections also apply to any of the Polly-O Excluded Contracts that an acquirer other than BelGioioso elects to have assigned under Paragraph V.K of the proposed Final Judgment.

Second, Paragraph V.M of the proposed Final Judgment requires Defendants, at the acquirer's option, to enter into a supply contract or contracts for the production and packaging of Polly-O Products sufficient to meet the acquirer's needs for a period of up to 12 months on terms and conditions reasonably related to market conditions for the production and packaging of Polly-O Products. As with the Athenos divestiture provisions above, supply contracts of this nature are common in this industry; indeed, Kraft Heinz today outsources much of its cheese production to other cheese manufacturers, including its ricotta cheese production. Companies operating in this industry have experience negotiating and managing these types of supply contracts, and such arrangements are used by other natural cheese brands. In addition, Paragraph V.M of the proposed Final Judgment prohibits employees of Defendants tasked with providing services pursuant to any supply contract from sharing any competitively sensitive information of the acquirer with any other employee of Defendants.

The acquirer may terminate any supply contract described in Paragraph V.M of the proposed Final Judgment, or any portion of any such supply contract, without cost or penalty at any time upon commercially reasonable written notice. The United States, in its sole discretion, may approve one or more extensions of any supply contract for up to an additional 12 months, and if the acquirer requests such an extension, Defendants must notify the United States in writing at least three months prior to the date the supply contract expires. Any amendments to or modifications of any provisions of a supply contract are subject to approval

by the United States, in its sole discretion.

Finally, Paragraph V.N of the proposed Final Judgment requires Defendants, at the acquirer's option and subject to approval by the United States in its sole discretion, to enter into a transition services agreement for a period of up to six months. Among other things, this transition services agreement will ensure that the acquirer has sufficient access to Polly-O-related enterprise data and personnel that are knowledgeable about this data, so as to avoid disruption to the Polly-O Divestiture Business while Defendants work to transfer this data to the acquirer and the acquirer interviews and makes offers of employment to Athenos personnel. The acquirer may terminate the transition services agreement, or any portion of it, without cost or penalty at any time upon commercially reasonable written notice. The United States, in its sole discretion, may approve one or more extensions of any transition services agreement for a total of up to an additional six months, and if the acquirer requests such an extension, Defendants must notify the United States in writing at least 30 days prior to the date the transition services agreement expires. Any amendments to or modifications of any provisions of a transition services agreement are also subject to approval by the United States, in its sole discretion. The employees of Defendants tasked with providing transition services must not share any competitively sensitive information of the acquirer of the Polly-O Divestiture Assets with any other employee of Defendants.

C. Divestiture Trustee Provisions

If Defendants do not accomplish the divestitures within the time periods prescribed in Paragraphs IV.A and V.A of the proposed Final Judgment, Section VI of the proposed Final Judgment provides that the Court will appoint a divestiture trustee selected by the United States to effect any remaining divestitures. If a divestiture trustee is appointed, the proposed Final Judgment provides that Defendants must pay all costs and expenses of the trustee. The divestiture trustee's commission must be structured so as to provide an incentive for the trustee based on the price obtained and the speed with which the divestiture is accomplished. After the divestiture trustee's appointment becomes effective, the trustee must provide monthly reports to the United States setting forth his or her efforts to accomplish the remaining divestitures. If the remaining divestitures have not been accomplished within six months of the divestiture trustee's appointment, the United States may make recommendations to the Court, which will enter such orders as appropriate, in order to carry out the purpose of the Final Judgment, including by extending the trust or the term of the divestiture trustee's appointment.

D. Ricotta Notification Requirement Provisions

Section XII of the proposed Final Judgment requires Lactalis to notify the United States at least 30 days in advance of acquiring, directly or indirectly, in a transaction that would not otherwise be reportable under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, 15 U.S.C. 18a (the ''HSR Act''), any assets or any interest in any entity involved in the sale of ricotta cheese to retailers in the United States. Pursuant to the proposed Final Judgment, Lactalis must notify the United States of such acquisitions as it would for a required HSR Act filing, as specified in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations, except that the information requested in Items 5 through 8 of the instructions must be provided only about the sale of ricotta cheese to retailers in the United States. The proposed Final Judgment further provides for waiting periods and opportunities for the United States to obtain additional information analogous to the provisions of the HSR Act before such acquisitions can be consummated.

The reason for this requirement for ricotta cheese is that there is evidence of strong regional variation in brand strength in ricotta cheese. Accordingly, Lactalis could purchase a regional brand of ricotta that is very important to competition in that particular region, but that purchase might be small enough on a national level not to require a filing under the HSR Act. Given Lactalis's strong presence in the sale of ricotta cheese nationwide, it is important for the United States to receive notice of regional transactions which could have the potential to substantially reduce competition in this industry. Requiring notification from Lactalis before acquisition of an entity involved in the sale of ricotta cheese to retailers will permit the United States to assess the competitive effects of that acquisition before it is consummated and, if necessary, seek to enjoin the transaction.

E. Compliance and Enforcement Provisions

The proposed Final Judgment also contains provisions designed to promote compliance with and make enforcement of the Final Judgment as effective as possible. Paragraph XV.A provides that the United States retains and reserves all rights to enforce the Final Judgment, including the right to seek an order of contempt from the Court. Under the terms of this paragraph, Defendants have agreed that in any civil contempt action, any motion to show cause, or any similar action brought by the United States regarding an alleged violation of the Final Judgment, the United States may establish the violation and the appropriateness of any remedy by a preponderance of the evidence and that Defendants have waived any argument that a different standard of proof should apply. This provision aligns the standard for compliance with the Final Judgment with the standard of proof that applies to the underlying offense that the Final Judgment addresses.

Paragraph XV.B provides additional clarification regarding the interpretation of the provisions of the proposed Final Judgment. The proposed Final Judgment is intended to remedy the loss of competition the United States alleges would otherwise result from the Transaction. Defendants agree that they will abide by the proposed Final Judgment and that they may be held in contempt of the Court for failing to comply with any provision of the proposed Final Judgment that is stated specifically and in reasonable detail, as interpreted in light of this procompetitive purpose.

Paragraph XV.C provides that if the Court finds in an enforcement proceeding that a Defendant has violated the Final Judgment, the United States may apply to the Court for an extension of the Final Judgment, together with such other relief as may be appropriate. In addition, to compensate American taxpayers for any costs associated with investigating and enforcing violations of the Final Judgment, Paragraph XV.C provides that, in any successful effort by the United States to enforce the Final Judgment against a Defendant, whether litigated or resolved before litigation, the Defendant must reimburse the United States for attorneys' fees, experts' fees, and other costs incurred in connection with that effort to enforce this Final Judgment, including the investigation of the potential violation.

Paragraph XV.D states that the United States may file an action against a Defendant for violating the Final Judgment for up to four years after the Final Judgment has expired or been terminated. This provision is meant to address circumstances such as when evidence that a violation of the Final

Judgment occurred during the term of the Final Judgment is not discovered until after the Final Judgment has expired or been terminated or when there is not sufficient time for the United States to complete an investigation of an alleged violation until after the Final Judgment has expired or been terminated. This provision, therefore, makes clear that, for four years after the Final Judgment has expired or been terminated, the United States may still challenge a violation that occurred during the term of the Final Judgment.

F. Term of the Final Judgment

Section XVI of the proposed Final Judgment provides that the Final Judgment will expire 10 years from the date of its entry, except that after five years from the date of its entry, the Final Judgment may be terminated upon notice by the United States to the Court and Defendants that the divestitures have been completed and that the continuation of this Final Judgment is no longer necessary or in the public interest.

IV. Remedies Available to Potential Private Plaintiffs

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment neither impairs nor assists the bringing of any private antitrust damage action. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. 16(a), the proposed Final Judgment has no prima facie effect in any subsequent private lawsuit that may be brought against Defendants.

V. Procedures Available for Modification of the Proposed Final Judgment

The United States and Defendants have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least 60 days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within 60 days of the date of publication of this Competitive Impact Statement in the **Federal Register**, or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the U.S. Department of Justice, which remains free to withdraw its consent to the proposed Final Judgment at any time before the Court's entry of the Final Judgment. The comments and the response of the United States will be filed with the Court. In addition, the comments and the United States' responses will be published in the **Federal Register** unless the Court agrees that the United States instead may publish them on the U.S. Department of Justice, Antitrust Division's internet website.

Written comments should be submitted in English to: Eric D. Welsh, Chief, Healthcare and Consumer Products Section, Antitrust Division, United States Department of Justice, 450 Fifth Street NW, Suite 4100, Washington, DC 20530.

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. Alternatives to the Proposed Final Judgment

As an alternative to the proposed Final Judgment, the United States considered a full trial on the merits against Defendants. The United States could have continued the litigation and sought preliminary and permanent injunctions against Lactalis's proposed acquisition of Kraft Heinz's natural cheese business in the United States. The United States is satisfied, however, that the relief required by the proposed Final Judgment will remedy the anticompetitive effects alleged in the Complaint, preserving competition for the sale of feta cheese sold to retailers in the United States and ricotta cheese sold to retailers in the New York Metro Market and in each of the Florida Metro Markets. Thus, the proposed Final Judgment achieves all or substantially all of the relief the United States would have obtained through litigation but avoids the time, expense, and uncertainty of a full trial on the merits.

VII. Standard of Review Under the APPA for the Proposed Final Judgment

Under the Clayton Act and APPA, proposed Final Judgments, or ''consent decrees,'' in antitrust cases brought by the United States are subject to a 60-day comment period, after which the Court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. 16(e)(1). In making that determination, the Court, in accordance with the statute as amended in 2004, is required to consider:

> (A) The competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and
>
> (B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1)(A) & (B). In considering these statutory factors, the Court's inquiry is necessarily a limited one as the government is entitled to ''broad discretion to settle with the defendant within the reaches of the public interest.'' *United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1461 (D.C. Cir. 1995); *United States* v. *U.S. Airways Grp., Inc.,* 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (explaining that the ''court's inquiry is limited'' in Tunney Act settlements); *United States* v. *InBev N.V./S.A.,* No. 08–1965 (JR), 2009 U.S. Dist. LEXIS 84787, at *3 (D.D.C. Aug. 11, 2009) (noting that a court's review of a proposed Final Judgment is limited and only inquires ''into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanisms to enforce the final judgment are clear and manageable'').

As the U.S. Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations in the government's Complaint, whether the proposed Final Judgment is sufficiently clear, whether its enforcement mechanisms are sufficient, and whether it may positively harm third parties. *See Microsoft,* 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the proposed Final Judgment, a court may not ''make de novo determination of facts and issues.'' *United States* v. *W. Elec. Co.,* 993 F.2d 1572, 1577 (D.C. Cir. 1993) (quotation marks omitted); *see also Microsoft,* 56 F.3d at 1460–62;

United States v. *Alcoa, Inc.,* 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 16 (D.D.C. 2000); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *3. Instead, ''[t]he balancing of competing social and political interests affected by a proposed antitrust decree must be left, in the first instance, to the discretion of the Attorney General.'' *W. Elec. Co.,* 993 F.2d at 1577 (quotation marks omitted). ''The court should also bear in mind the *flexibility* of the public interest inquiry: The court's function is not to determine whether the resulting array of rights and liabilities is one that will *best* serve society, but only to confirm that the resulting settlement is within the *reaches* of the public interest.'' *Microsoft,* 56 F.3d at 1460 (quotation marks omitted); *see also United States* v. *Deutsche Telekom AG,* No. 19–2232 (TJK), 2020 WL 1873555, at *7 (D.D.C. Apr. 14, 2020). More demanding requirements would ''have enormous practical consequences for the government's ability to negotiate future settlements,'' contrary to congressional intent. *Microsoft,* 56 F.3d at 1456. ''The Tunney Act was not intended to create a disincentive to the use of the consent decree.'' *Id.*

The United States' predictions about the efficacy of the remedy are to be afforded deference by the Court. *See, e.g., Microsoft,* 56 F.3d at 1461 (recognizing courts should give ''due respect to the Justice Department's . . . view of the nature of its case''); *United States* v. *Iron Mountain, Inc.,* 217 F. Supp. 3d 146, 152–53 (D.D.C. 2016) (''In evaluating objections to settlement agreements under the Tunney Act, a court must be mindful that [t]he government need not prove that the settlements will perfectly remedy the alleged antitrust harms[;] it need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' (internal citations omitted)); *United States* v. *Republic Servs., Inc.,* 723 F. Supp. 2d 157, 160 (D.D.C. 2010) (noting ''the deferential review to which the government's proposed remedy is accorded''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (''A district court must accord due respect to the government's prediction as to the effect of proposed remedies, its perception of the market structure, and its view of the nature of the case.''). The ultimate question is whether ''the remedies [obtained by the Final Judgment are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest.' '' *Microsoft,* 56 F.3d at 1461 (*quoting W. Elec. Co.,* 900 F.2d at 309).

Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint, and does not authorize the Court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459; *see also U.S. Airways,* 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *20 (''[T]he 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged.''). Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Microsoft,* 56 F.3d at 1459–60.

In its 2004 amendments to the APPA, Congress made clear its intent to preserve the practical benefits of using judgments proposed by the United States in antitrust enforcement, Public Law 108–237 § 221, and added the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. 16(e)(2); *see also U.S. Airways,* 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it first enacted the Tunney Act in 1974. As Senator Tunney explained: ''[T]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). ''A court can make its public interest determination based on the competitive impact statement and response to public comments alone.'' *U.S. Airways,* 38 F. Supp. 3d at 76 (citing *Enova Corp.,* 107 F. Supp. 2d at 17).

VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: December 20, 2021

Respectfully submitted,

For Plaintiff United States of America:

Justin M. Dempsey (D.C. Bar #425976), Trial Attorney, United States Department of Justice, Antitrust Division, Healthcare and Consumer Products Section, 450 Fifth Street NW, Suite 4100, Washington, DC 20530, Telephone: (202) 307–5815, Email: *Justin.Dempsey@usdoj.gov.*

[FR Doc. 2021–27959 Filed 12–23–21; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–0094]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension With Change, of a Previously Approved Collection; Applications for Special Deputation

AGENCY: U.S. Marshals Service, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), U.S. Marshals Service (USMS), will submit 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 60 days until February 25, 2022.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, particularly with respect to the estimated public burden or associated response time, have suggestions, need a copy of the proposed information collection instrument with instructions, or desire any additional information, please contact Nicole Timmons either by mail at CG–3, 10th Floor, Washington, DC 20530–0001, by email at *Nicole.Timmons@usdoj.gov,* or by telephone at 202–236–2646.

SUPPLEMENTARY INFORMATION: 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;
—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; 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.

Overview of this information collection:

1. *Type of Information Collection (check justification or form 83):* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* Applications for Special Deputation.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form number (if applicable): USM–3A and USM–3C.

Component: U.S. Marshals Service, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Federal government and State/local government.

Abstract: The collection of information for these forms is authorized by 28 U.S.C. 562. The USMS is authorized to deputize selected persons to perform the functions of a Special Deputy U.S. Marshal whenever the law enforcement needs of the USMS so require and as designated by the Associate Attorney General pursuant to 28 CFR 0.19(a)(3). USMS Special Deputation files serve as a centralized record of the special deputations granted by the USMS to assist in tracking, controlling and monitoring the Special Deputation Program.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 6,000 respondents will complete a 15 minute form (Form USM–3A) and 5,500 respondents will complete a 10 minute form (Form USM–3C).

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated public burden associated with this collection is 2,417 hours. It is estimated that applicants will take 15 minutes to complete a Form USM–3A and 10 minutes to complete a Form USM–3C. In order to calculate the public burden for Form USM–3A, USMS multiplied 15 by 6,000 and divided by 60 (the number of minutes in an hour), which equals 1,500 total annual burden hours. In order to calculate the public burden for Form USM–3C, USMS multiplied 10 by 5,500 and divided by 60 (the number of minutes in an hour), which equals 917 total annual burden hours. In sum there are an estimated 2,417 total annual public burden hours associated with this collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: December 21, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–27996 Filed 12–23–21; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0028]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 30-day notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) 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 January 26, 2022.

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.

SUPPLEMENTARY INFORMATION: 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:

(1) 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;

(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) Enhance the quality, utility, and clarity of the information to be collected; and

(4) 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.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Semi-annual Progress Report for Children and Youth Exposed to Violence Program.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0028. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 25 grantees under the Consolidated Grant Program to Address Children and Youth Experiencing Domestic and Sexual Assault and Engage Men and Boys as Allies (hereafter referred to as the Consolidated Youth Program) enacted in the FY 2012–2018 appropriation acts, which consolidated four previously authorized and appropriated programs into one comprehensive program. The four programs included in these consolidations were: Services to Advocate for and Respond to Youth (Youth Services), Grants to Assist Children and Youth Exposed to Violence (CEV), Engaging Men and Youth in Preventing Domestic Violence (EMY), and Supporting Teens through Education and Prevention (STEP).

The Consolidated Youth Program supports projects designed to provide coordinated community responses that

support child, youth and young adult victims through direct services, training, coordination and collaboration, effective intervention, treatment, response, and prevention strategies. The Consolidated Youth Program creates a unique opportunity for communities to increase collaboration among non-profit victim service providers; violence prevention, and children (0–10), youth (11–18), young adult (19–24) and men-serving organizations; tribes and tribal governments; local government agencies; schools; and programs that support men's role in combating sexual assault, domestic violence, dating violence and stalking.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the approximately 25 respondents (grantees from the Consolidated Youth Program) approximately one hour to complete a semi-annual progress report. The semi-annual progress report is divided into sections that pertain to the different types of activities in which grantees may engage. A Consolidated Youth Program grantee will only be required to complete the sections of the form that pertain to its own specific activities.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection forms is 50 hours, that is 25 grantees completing a form twice a year with an estimated completion time for the form being one hour.

If additional information is required contact: Melody Braswell, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E, 405B, Washington, DC 20530.

Dated: December 21, 2021.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2021–27997 Filed 12–23–21; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0021]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) 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 January 26, 2022.

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.

SUPPLEMENTARY INFORMATION: 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:

(1) 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;

(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) Enhance the quality, utility, and clarity of the information to be collected; and

(4) 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.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Semi-Annual Progress Report for Grantees from Grants to Enhance Culturally and Linguistically Specific Services for Victims of Domestic Violence, Dating Violence, Sexual Assault, and Stalking Program (Culturally and Linguistically Specific Services Program).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122- 0021. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 50 grantees of the Culturally and Linguistically Specific Services Program. The program funds projects that promote the maintenance and replication of existing successful domestic violence, dating violence, sexual assault, and stalking community-based programs providing culturally and linguistically specific services and other resources. The program also supports the development of innovative culturally and linguistically specific strategies and projects to enhance access to services and resources for victims of violence against women.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the approximately 50 respondents (Culturally and Linguistically Specific Services Program grantees) approximately one hour to complete a semi-annual progress report. The semi-annual progress report is divided into sections that pertain to the different types of activities in which grantees may engage. A Culturally and Linguistically Specific Services Program grantee will only be required to complete the sections of the form that pertain to its own specific activities.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection forms is 100 hours, that is 50 grantees completing a form twice a year with an estimated completion time for the form being one hour.

If additional information is required contact: Melody Braswell, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E, 405B, Washington, DC 20530.

Dated: December 21, 2021.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2021–27999 Filed 12–23–21; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

[OMB Number 1110–0071]

Agency Information Collection Activities; Proposed eCollection eComments Request; National Use-of-Force Data Collection: Extension of a Currently Approved Collection

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice, Federal Bureau of Investigation's (FBI's) Criminal Justice Information Services (CJIS) Division is 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 January 26, 2022.

ADDRESSES: Please note: The most current renewal documentation for the National Use-of-Force Data Collection has been updated and is available for review on *reginfo.gov* under OMB No. 1110–0071.

Written comments and suggestions regarding the items contained in this notice, especially the estimated burden and associated response time, may be sent for consideration in a number of ways. 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.

SUPPLEMENTARY INFORMATION:

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 FBI, 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.
- Evaluate whether, and if so, how the quality, utility, and clarity of the information to be collected can be enhanced.
- 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.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *The Title of the Form/Collection:* National Use-of-Force Data Collection.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number is 1110–0071. Sponsor: CJIS Division, FBI, Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Federal, state, local, and tribal law enforcement agencies.

Abstract: The FBI has a long-standing tradition of collecting data and providing statistics concerning Law Enforcement Officers Killed and Assaulted (LEOKA) and justifiable homicides. To provide a better understanding of the incidents of use of force by law enforcement, the Uniform Crime Reporting (UCR) Program developed a new data collection for law enforcement agencies to provide information on incidents where use of force by a law enforcement officer has led to the death or serious bodily injury of a person, as well as when a law enforcement officer discharges a firearm at or in the direction of a person.

When a use-of-force incident occurs, federal, state, local, and tribal law enforcement agencies provide information to the data collection on characteristics of the incident, subjects of the use of force, and the officers who applied force in the incident. Agencies positively affirm, on a monthly basis, whether their agency did or did not have a use-of-force incident that resulted in a fatality, a serious bodily injury to a person, or a firearm discharge at or in the direction of a person. When no use-of-force incident occurs in a month, agencies submit a zero report. Enrollment information from agencies and state points of contact is collected when the agency or contact initiates participation in the data collection. Enrollment information is updated no less than annually to assist with managing this data.

The new data collection defines a law enforcement officer using the current LEOKA definition: ''All federal, state, county, and local law enforcement officers (such as municipal, county police officers, constables, state police, highway patrol, sheriffs, their deputies, federal law enforcement officers, marshals, special agents, etc.) who are sworn by their respective government authorities to uphold the law and to safeguard the rights, lives, and property of American citizens. They must have full arrest powers and be members of a public governmental law enforcement agency, paid from government funds set aside specifically for payment to sworn police law enforcement organized for the purposes of keeping order and for preventing and detecting crimes, and apprehending those responsible.''

The definition of ''serious bodily injury'' is based, in part, on Title 18 United States Code, Section 2246 (4), to mean ''bodily injury that involves a substantial risk of death, unconsciousness, protracted and obvious disfigurement, or protracted loss or impairment of the function of a bodily member, organ, or mental faculty.'' These actions include the use of a firearm; an electronic control weapon (*e.g.,* Taser); an explosive device; a pepper or OC (oleoresin capsicum) spray or other chemical agent; a baton; an impact projectile; a blunt instrument; hands-fists-feet; or a canine.

(5) *A total number of respondents and the amount of time estimated for an average respondent to respond:* As of June 2020, a total of 6,837 agencies covering 439,936 law enforcement officers were enrolled in the National Use-of-Force Data Collection. The burden hours per incident are estimated to be 0.63 of an hour (around 38 minutes) for completion per incident.

(6) *An estimate of the total public burden (in hours) associated with the collection:* Burden estimates are based on sources from the FBI's UCR Program, the Bureau of Justice Statistics (BJS), and the Centers for Disease Control and Prevention (CDC). The BJS recently estimated that approximately 1,400 fatalities attributed to a law enforcement use of force occur annually (Planty, et al., 2015, *Arrest-Related Deaths Program: Data Quality Profile, http://www.bjs.gov/index.cfm?ty=pbdetail&iid=5260*). In addition, the CDC estimates the incidences of fatal and nonfatal injury—including those due to legal intervention—from emergency department data. In their study, *The real risks during deadly police shootouts: Accuracy of the naïve shooter,* Lewinski, et al., (2015) estimate law enforcement officers miss their target approximately 50 percent of the time at the firing range. This information was

used to develop a simple estimate for the number of times officers discharge a firearm at or in the direction of a person but do not strike the individual. In addition, the UCR Program collects counts of the number of sworn and civilian law enforcement employees in the nation's law enforcement agencies.

The following table shows burden estimates based on previous estimation criteria and current National Use-of-Force Data Collection enrollment numbers.

ESTIMATED BURDEN FOR ALL LAW ENFORCEMENT AGENCIES IN ANNUAL COLLECTION

Timeframe	Reporting group	Approximate number of officers from participating agencies	Maximum per capita rate of use-of-force occurrence per officer	Minimum per capita rate of use-of-force occurrence per officer	Maximum estimated number of incidents	Minimum estimated number of incidents	Estimated burden hours per incident	Maximum estimate total number of burden hours	Minimum estimate total number of burden hours
Collection (Annual).	All agencies submitting data.	488,600	0.122	0.012	59,609	5,863	0.63	37,554	3,694

Based on previous estimation criteria and enrollment numbers as of October 5, 2021, the FBI is requesting 37,554 burden hours for the annual collection of this data. This reflects a slight change from the previously published 60-day public notice, as participation in the National Use-of-Force Data Collection is continuing to increase.

If additional information is required, contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: December 21, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–27995 Filed 12–23–21; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1110–0009]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Law Enforcement Officers Killed and Assaulted Program, Analysis of Officers Feloniously Killed and Assaulted; and Law Enforcement Officers Killed and Assaulted Program, Analysis of Officers Accidentally Killed

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice, Federal Bureau of Investigation, Criminal Justice Information Services Division, will be submitting the following information collection request to the Office of Management and Budget for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until February 25, 2022.

FOR FURTHER INFORMATION CONTACT: All comments, suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Linda Shriver, Acting Unit Chief, Federal Bureau of Investigation, Criminal Justice Information Services Division, Module D–1, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306.

SUPPLEMENTARY INFORMATION: 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 Federal Bureau of Investigation, 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

Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced

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.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *The Title of the Form/Collection:* Law Enforcement Officers Killed and Assaulted Program, Analysis of Officers Feloniously Killed and Assaulted Program; and Law Enforcement Officers Killed and Assaulted, Analysis of Officers Accidentally Killed.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number is 1–701 and 1–701a. The applicable component within the Department of Justice is the Criminal Justice Information Services Division, in the Federal Bureau of Investigation.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Federal, state, county, city, local, and tribal law enforcement agencies.

Abstract: Under Title 28, U.S. Code, Section 534, Acquisition, Preservation, and Exchange of Identification Records; Appointment of Officials this collection requests the number of officers killed or assaulted from law enforcement agencies in order for the Federal Bureau of Investigation Uniform Crime Reporting Program to serve as the national clearinghouse for the collection and dissemination of law enforcement officer death/assault data and to publish these statistics in Law Enforcement Officers Killed and Assaulted.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* Uniform Crime Reporting Participation Burden Estimation: For 2020, there were approximately 189 law enforcement agency respondents with an estimated response time of 1 hour per report.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are approximately 189

hours, annual burden, associated with this information collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: December 21, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–27994 Filed 12–23–21; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0022]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 30-day notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) 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 January 26, 2022.

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.

SUPPLEMENTARY INFORMATION: 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:

(1) 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;

(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) Enhance the quality, utility, and clarity of the information to be collected; and

(4) 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.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Annual Progress Report for the Sexual Assault Services Formula Grant Program (SASP).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0022. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 606 administrators and subgrantees of the SASP. SASP grants support intervention, advocacy, accompaniment, support services, and related assistance for adult, youth, and child victims of sexual assault, family and household members of victims, and those collaterally affected by the sexual assault. The SASP supports the establishment, maintenance, and expansion of rape crisis centers and other programs and projects to assist those victimized by sexual assault. The grant funds are distributed by SASP state administrators to subgrantees as outlined under the provisions of the Violence Women Act.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the approximately 606 respondents (SASP administrators and subgrantees) approximately one hour to complete an annual progress report. The annual progress report is divided into sections that pertain to the different types of activities in which subgrantees may engage. A SASP subgrantee will only be required to complete the sections of the form that pertain to its own specific activities.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection form is 606 hours, that is 606 administrators and subgrantees completing a form once a year with an estimated completion time for the form being one hour.

If additional information is required contact: Melody Braswell, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E, 405B, Washington, DC 20530.

Dated: December 21, 2021.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2021–27998 Filed 12–23–21; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation and Liability Act

On December 15, 2021, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Southern District of Texas in the lawsuit entitled *United States* v. *Sea Lion Chemical Technology, Inc. and Sea Lion, Inc., Case No. 3:21–cv–347.* The proposed Consent Decree resolves the United States' claims, on behalf of the Environmental Protection Agency, under Section 107(a) of the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA''), 42 U.S.C. 9607(a), against Sea Lion Chemical Technology, Inc. and its parent Sea Lion, Inc. (collectively ''Sea Lion'') for their liability at the Malone Service Company Superfund Site (the ''Site'') located in Texas City, Galveston County, Texas. Under the proposed settlement, Sea Lion has agreed to pay $2,987,353.53 to resolve its liability.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Sea Lion Chemical Technology, Inc. and Sea Lion, Inc., Case No. 3:21–cv–347,* D.J. Ref. No. 90–11–2–07465/8. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $6.25 (25 cents per page reproduction cost) payable to the United States Treasury.

Thomas Carroll,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2021–28027 Filed 12–23–21; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation and Liability Act

On December 16, 2021, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Southern District of Illinois in the lawsuit entitled *United States* v. *Alcoa Corporation, et al.,* Civil Action No. 21–1694.

The United States filed a Complaint in this lawsuit under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). The United States' complaint names Alcoa Corporation and the City of East St. Louis, Illinois as defendants. The complaint requests recovery of oversight and other response costs that the United States incurred and will incur in connection with remedial efforts taken at the former aluminum production plant on Missouri Avenue in East St. Louis, Illinois that Alcoa Incorporated operated from 1903 to 1957. The complaint also seeks an order requiring defendants to implement remedial work at Operable Unit 2 of the North Alcoa Superfund Alternative Site as selected by the U.S. Environmental Protection Agency in a Record of Decision issued in June 2020. The defendants and Howmet Aerospace, Inc., a company created after the separation of Alcoa Incorporated in 2016, signed the proposed Consent Decree agreeing to complete the work, estimated to cost $4.1 million, and to pay all of the United States' future response costs at the site. In return, the United States agrees not to sue the defendants or Howmet under sections 106 and 107 of CERCLA related to this work.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Alcoa Corporation, et al.,* D.J. Ref. No. 90–11–3–10590/1. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the proposed Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $45.75 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without Appendix A (the Record of Decision), the cost is only $24.50.

Patricia Mckenna,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2021–27988 Filed 12–23–21; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Employment and Training Administration

Determinations Regarding Eligiblity to Apply for Trade Adjustment Assistance

In accordance with Sections 223 and 284 (19 U.S.C. 2273 and 2395) of the Trade Act of 1974 (19 U.S.C. 2271, *et seq.*) (''Act''), as amended, the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance under Chapter 2 of the Act (''TAA'') for workers by (TA–W) issued during the period of *November 1, 2021 through November 30, 2021.*

This notice includes summaries of initial determinations such as Affirmative Determinations of Eligibility, Negative Determinations of Eligibility, and Determinations Terminating Investigations of Eligibility within the period. If issued in the period, this notice also includes summaries of post-initial determinations that modify or amend initial determinations such as Affirmative Determinations Regarding Applications for Reconsideration, Negative Determinations Regarding Applications for Reconsideration, Revised Certifications of Eligibility, Revised Determinations on Reconsideration, Negative Determinations on Reconsideration, Revised Determinations on remand from the Court of International Trade, and Negative Determinations on remand from the Court of International Trade.

Affirmative Determinations for Trade Adjustment Assistance

The following certifications have been issued.

TA–W No.	Subject firm	Location	Reason(s)
96,977	Rest Assured	Rochester, MN	ITC Determination.
97,003	Microsoft Corporation	Fargo, ND	Shift in Production to a Foreign Country.
97,111	PolymerPak, LLC	Visalia, CA	ITC Determination.
98,008	QuarterNorth Energy LLC	Houston, TX	Increased Customer Imports.

TA–W No.	Subject firm	Location	Reason(s)
98,034	Trinity Tank Car, Inc	Longview, TX	Shift in Production to an FTA Country or Beneficiary.
98,044	The Watt Stopper	Orem, UT	Shift in Production to an FTA Country or Beneficiary.
98,050	Arcosa Wind Towers, Inc	Clinton, IL	Increased Customer Imports.
98,058	Arcosa Wind Towers, Inc	Newton, IA	Increased Customer Imports.
98,072	Malteurop North America	Milwaukee, WI	Shift in Production to an FTA Country or Beneficiary.
98,075	AVX Filters Corporation, Sun Valley Filter Division.	Sun Valley, CA	Shift in Production to an FTA Country or Beneficiary.
98,084	New York Air Brake, LLC	Watertown, NY	Shift in Production to an FTA Country or Beneficiary.
98,103	Aquiline Drones Corporation	Hartford, CT	Increased Company Imports.

Negative Determinations for Trade Adjustment Assistance

The following investigations revealed that the eligibility criteria for TAA have not been met for the reason(s) specified.

TA–W No.	Subject firm	Location	Reason(s)
95,815	Knoll, Inc	Grand Rapids, MI	No Shift in Production or Other Basis.
96,795	Electrical GeoDesics, Inc., d/b/a Philips Neuro	Eugene, OR	No Shift in Production or Other Basis.
97,104	Wyoming Machinery Company	Casper, WY	No Shift in Services or Other Basis.
97,104A	Wyoming Machinery Company	Gillette, WY	No Shift in Services or Other Basis.
97,104B	Wyoming Machinery Company	Cheyenne, WY	No Shift in Services or Other Basis.
97,104C	Wyoming Machinery Company	Rock Springs, WY	No Shift in Services or Other Basis.
98,052	Grass Valley USA, LLC	Hillsboro, OR	Workers Do Not Produce an Article.
98,054	Elsevier Inc	Maryland Heights, MO	Workers Do Not Produce an Article.
98,059	Ascension Technologies	Indianapolis, IN	Workers Do Not Produce an Article.
98,061	Trinseo LLC	Midland, MI	No Sales or Production Decline/Shift in Production (Domestic Transfer).
98,067	Diva Hair Deals	Columbia, MD	Workers Do Not Produce an Article.
98,069	Auto Injury Solutions Inc	Iselin, NJ	Workers Do Not Produce an Article.
98,074	Mass General Brigham	Somerville, MA	Workers Do Not Produce an Article.
98,094	Classic Brands, LLC	Jessup, MD	No Import Increase and/or Production Shift Abroad.
98,099	Staffmark Investment LLC	Santa Ana, CA	Workers Do Not Produce an Article.

Determinations Terminating Investigations for Trade Adjustment Assistance

The following investigations were terminated for the reason(s) specified.

TA–W No.	Subject firm	Location	Reason(s)
97,080	BCS Automotive Interface Solutions U.S., LLC	Auburn, NY	Existing Certification in Effect.
98,035	AT&T Services, Inc	Bothell, WA	Existing Certification in Effect.
98,078	Gannett Co., Inc	Fort Smith, AR	Ongoing Investigation in Process.

Revised Certifications of Eligibility

The following revised certifications of eligibility to apply for TAA have been issued.

TA–W No.	Subject firm	Location	Reason(s)
96,994	AT&T Services, Inc	Oakton, VA	Worker Group Clarification.

I hereby certify that the aforementioned determinations were issued during the period of *November 1, 2021 through November 30, 2021.* These determinations are available on the Department's website *https://www.dol.gov/agencies/eta/tradeact* under the searchable listing determinations or by calling the Office

of Trade Adjustment Assistance toll free at 888–365–6822.

Signed at Washington, DC, this 10th day of December 2021.

Hope D. Kinglock,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2021–27982 Filed 12–23–21; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Eligiblity To Apply for Trade Adjustment Assistance

In accordance with the Trade Act of 1974 (19 U.S.C. 2271, *et seq.*) (''Act''), as amended, the Department of Labor herein presents notice of investigations regarding eligibility to apply for trade adjustment assistance under chapter 2 of the Act (''TAA'') for workers by (TA–W) started during the period of *November 1, 2021 through November 30, 2021.*

This notice includes instituted initial investigations following the receipt of validly filed petitions. Furthermore, if applicable, this notice includes investigations to reconsider negative initial determinations or terminated initial investigations following the receipt of a valid application for reconsideration.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under title II, chapter 2, of the Act. Any persons showing a substantial interest in the subject matter of the investigations may request a public hearing provided such request is filed in writing with the Administrator, Office of Trade Adjustment Assistance, at the address shown below, no later than ten days after publication in **Federal Register**.

Initial Investigations

The following are initial investigations commenced following the receipt of a properly filed petition.

TA–W–No.	Subject firm	Location	Inv start date
98,101	Laminate Technologies of Oregon	White City, OR	11/2/2021
98,102	1Concier	McCormick, SC	11/3/2021
98,103	Aquiline Drones Corporation	Hartford, CT	11/3/2021
98,104	Baxter Healthcare	Brooklyn Park, MN	11/3/2021
98,105	Kemper Valve and Fittings Corp	Pleasanton, TX	11/3/2021
98,106	Safran Cabin Inc.	Ontario, CA	11/4/2021
98,107	Wells Fargo Bank N.A	Orlando, FL	11/4/2021
98,108	West Penn Wire	Washington, PA	11/4/2021
98,109	FDP Virginia, Inc	Tappahannock, VA	11/5/2021
98,110	TE Connectivity	Norwood, MA	11/5/2021
98,111	Medtronic	Minneapolis, MN	11/8/2021
98,112	Nonmetallic Machinery Assembly, Inc.	Erie, PA	11/8/2021
98,113	CitiBank	Sioux Falls, SD	11/9/2021
98,114	Kellogg Company	Battle Creek, MI	11/9/2021
98,115	Rogue Truck Body	Kerby, OR	11/9/2021
98,116	Ascenda USA Inc., d/b/a 24–7 Intouch	Aurora, CO	11/10/2021
98,117	Lear Corporation	Roscommon, MI	11/10/2021
98,118	Setterstix	Cattaraugus, NY	11/10/2021
98,119	Cardinal Health	Whitestone, NY	11/12/2021
98,120	Conesys Inc	Torrance, CA	11/19/2021
98,121	Borg Warner Transmission Systems	Frankfort, IL	11/22/2021
98,122	Redsail West Technologies (Integra)	Anacortes, WA	11/23/2021
98,123	K2 Advisors, LLC	Stamford, CT	11/24/2021
98,124	Linwood Mining and Minerals Corp	Davensport, IA	11/24/2021
98,125	Multi-Color Global Label Solutions	Fulton, NY	11/24/2021
98,126	N26 Inc.	New York, NY	11/24/2021
98,127	Pilgrim Nuclear Power Station	Plymouth, MA	11/30/2021
98,128	Rebecca Taylor, Inc	New York, NY	11/30/2021

Reconsideration Investigations

The following are reconsideration investigations following the receipt of a properly filed application for reconsideration.

TA–W–No.	Subject firm	Location	Inv start date
97,007	T-Mobile USA, Inc	Honolulu, HI	11/17/2021

A record of these investigations and petitions filed are available, subject to redaction, on the Department's website *https://www.dol.gov/agencies/eta/tradeact* under the searchable listing or by calling the Office of Trade Adjustment Assistance toll free at 888–365–6822.

Signed at Washington, DC this 10th day of December 2021.

Hope D. Kinglock

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2021–27983 Filed 12–23–21; 8:45 am]

BILLING CODE 4510–FN–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (21–089)]

NASA Advisory Council; Human Exploration and Operations Committee

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Human Exploration and Operations Committee of the NASA Advisory Council (NAC). This Committee reports to the NAC.

DATES: Tuesday, January 18, 2022, 10:00 a.m. to 12:30 p.m. Eastern Time; and Wednesday, January 19, 2022, 8:30 a.m. to 4:30 p.m. Eastern Time.

ADDRESSES: Meeting will be virtual only. See Webex and audio dial-in information below under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Dr. Bette Siegel, Designated Federal Officer, Human Exploration and Operations Committee, NASA Headquarters, Washington, DC 20546, via email at *bette.siegel@nasa.gov* or phone at 202–358–2245.

SUPPLEMENTARY INFORMATION: As noted above, this meeting will be open to the public via Webex and telephonically. Webex connectivity information is provided below. For audio, when you join the Webex event, you may use your computer or provide your phone number to receive a call back, otherwise, call the U.S. toll conference number listed.

The event address for January 18, 2022 is: *https://nasaenterprise.webex.com/nasaenterprise/j.php?MTID=mc8f95e657f7ccc1478978a86379dc47d.*

The event number (access code) is 2764 200 1053, and the event password is MPbDQ3tD@62 (67237383 from phones). To join by phone: +1–929–251–9612 (USA Toll 2), or +1–415–527–5035 (US Toll) global call-in numbers.

The event address for January 19, 2022 is: *https://nasaenterprise.webex.com/nasaenterprise/j.php?MTID=m7bfa4e695f07e0149f496ecad1c16789.*

The event number (access code) is 2762 086 1702, and the event password is MngP4vkG@63 (66474854 from phones). To join by phone: +1–929–251–9612 (USA Toll 2), or 1–415–527–5035 (US Toll) global call-in numbers.

The agenda for the meeting includes the following topics:

—Space Operations Mission Directorate (SOMD)/Exploration Systems Mission Directorate (ESDMD) Status
—International Space Station Update
—Commercial Spaceflight Division Status
—Commercial Crew Program Status
—Systems Engineering and Integration
—Exploration Systems Development
—Advanced Exploration Systems

It is imperative that this meeting be held on this day to accommodate the scheduling priorities of the key participants.

Patricia Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2021–28062 Filed 12–23–21; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (21–090)]

Notice of Intent To Grant an Exclusive, Co-Exclusive or Partially Exclusive Patent License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of intent to grant exclusive, co-exclusive or partially exclusive patent license.

SUMMARY: NASA hereby gives notice of its intent to grant an exclusive, co-exclusive or partially exclusive patent license to practice the inventions described and claimed in the patents and/or patent applications listed in **SUPPLEMENTARY INFORMATION** below.

DATES: The prospective exclusive, co-exclusive or partially exclusive license may be granted unless NASA receives written objections including evidence and argument, no later than January 11, 2022 that establish that the grant of the license would not be consistent with the requirements regarding the licensing of federally owned inventions as set forth in the Bayh-Dole Act and implementing regulations. Competing applications completed and received by NASA no later than January 11, 2022 will also be treated as objections to the grant of the contemplated exclusive, co-exclusive or partially exclusive license. Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act.

Objections and Further Information: Written objections relating to the prospective license or requests for further information may be submitted to Agency Counsel for Intellectual Property, NASA Headquarters at Email: *hq-patentoffice@mail.nasa.gov.* Questions may be directed to Phone: (202) 358–3437.

SUPPLEMENTARY INFORMATION: NASA intends to grant an exclusive, co-exclusive, or partially exclusive patent license in the United States to practice the inventions described and claimed in: U.S. Patent No. 8,448,498 titled ''Hermetic Seal Leak Detection Apparatus,'' U.S. Patent No. 9,097,609 titled ''Hermetic Seal Leak Detection Apparatus with Variable Size Test Chamber,'' U.S. Patent No. 8,813,577 and 8,555,731 titled ''Self-Contained Compressed-Flow Generation Device for Use in Making Differential Measurements,'' U.S. Patent No. 8,739,638 titled ''Star-Shaped Fluid Flow Tool for Use in Making Differential Measurements,'' U.S. Patent No. 8,733,180 titled ''Airfoil-Shaped Fluid Flow Tool for Use in Making Differential Measurements,'' and U.S. Patent No. 9,046,115 and 9,016,928 titled ''Eddy Current Minimizing Flow Plug for Use in Flow Conditioning and Flow Metering,'' to Excellerators, LLC, having its principal place of business in Dyersburg, TN. The fields of use may be limited. NASA has not yet made a final determination to grant the requested license and may deny the requested license even if no objections are submitted within the comment period. This notice of intent to grant an exclusive, co-exclusive or partially exclusive patent license is issued in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i). The patent rights in these inventions have been assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The prospective license will comply with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Information about other NASA inventions available for licensing can be

found online at *http://technology.nasa.gov.*

Helen M. Galus,

Agency Counsel for Intellectual Property.

[FR Doc. 2021–28076 Filed 12–23–21; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2022–018]

State, Local, Tribal, and Private Sector Policy Advisory Committee (SLTPS–PAC); Meeting

AGENCY: Information Security Oversight Office (ISOO), National Archives and Records Administration (NARA).

ACTION: Notice of federal advisory committee meeting.

SUMMARY: We are announcing an upcoming meeting of the State, Local, Tribal, and Private Sector Policy Advisory Committee (SLTPS–PAC) in accordance with the Federal Advisory Committee Act and implementing regulations.

DATES: The meeting will be on January 26, 2022, from 10:00 a.m. to 12:00 p.m. ET.

ADDRESSES: This meeting will be a virtual meeting. We will send instructions on how to access it to those who register according to the instructions below.

FOR FURTHER INFORMATION CONTACT: Heather Harris Pagán, ISOO Senior Program Analyst, by email at *heather.harrispagan@nara.gov* or by telephone at 202.357.5351. Contact ISOO at *ISOO@nara.gov.*

SUPPLEMENTARY INFORMATION: This virtual meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. app 2) and implementing regulations at 41 CFR 101–6. The Committee will discuss matters relating to the classified national security information program for state, local, tribal, and private sector entities.

Procedures: Please submit the name, email address, and telephone number of people planning to attend to Heather Harris Pagán at ISOO (contact information above) no later than 9:00 a.m. Wednesday, January 26, 2022. We will provide meeting access information to those who register.

Tasha Ford,

Committee Management Officer.

[FR Doc. 2021–27954 Filed 12–23–21; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL TRANSPORTATION SAFETY BOARD

[Docket No.: NTSB–2021–0010, OMB Control No. 3147–0028]

Proposed Information Collection; Comment Request

Correction

In notice document 2021–27299, appearing on page 71676 in the issue of Friday, December 17, 2021, make the following corrections:

1. On page 71676, in the first column, in the **ADDRESSES** section, on the third line, ''NTSB–2021–0007'' should read, ''NTSB–2021–0010''.

2. On the same page, in the same column, in the paragraph that begins ''Instructions:'', on the third line, ''NTSB–2021–0007'' should read, ''NTSB–2021–0010''.

3. On the same page, in the same column, in the paragraph that begins ''Docket:'', on the fourth line, ''NTSB–2021–0007'' should read, ''NTSB–2021–0010''.

4. On the same page, in the same column, in the same paragraph, on the seventh and eighth lines, ''NTSB–2021–0007'' should read, ''NTSB–2021–0010''.

[FR Doc. C1–2021–27299 Filed 12–23–21; 8:45 am]

BILLING CODE 0099–10–D

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of December 27, 2021, January 3, 10, 17, 24, 31, 2022.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

MATTERS TO BE CONSIDERED:

Week of December 27, 2021

There are no meetings scheduled for the week of December 27, 2021.

Week of January 3, 2022—Tentative

There are no meetings scheduled for the week of January 3, 2022.

Week of January 10, 2022—Tentative

There are no meetings scheduled for the week of January 10, 2022.

Week of January 17, 2022—Tentative

There are no meetings scheduled for the week of January 17, 2022.

Week of January 24, 2022—Tentative

Thursday, January 27, 2022

9:00 a.m. Strategic Programmatic Overview of the Decommissioning and Low-Level Waste and Nuclear Materials Users Business Lines (Public Meeting) (Contact: Celimar Valentin-Rodriguez: 301–415–7124)

Additional Information: The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/.* For those who would like to attend in person, note that all visitors are required to complete the NRC Self-Health Assessment and Certification of Vaccination forms. Visitors who certify that they are not fully vaccinated or decline to complete the certification must have proof of a negative Food and Drug Administration-approved polymerase chain reaction (PCR) or Antigen (including rapid tests) COVID–19 test specimen collection from no later than the previous 3 days prior to entry to an NRC facility. The forms and additional information can be found here *https://www.nrc.gov/about-nrc/covid-19/guidance-for-visitors-to-nrc-facilities.pdf.*

Week of January 31, 2022—Tentative

There are no meetings scheduled for the week of January 31, 2022.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at

Tyesha.Bush@nrc.gov or *Betty.Thweatt@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: December 22, 2021.

For the Nuclear Regulatory Commission.

Sergio E. Gonzalez,

Information Management Specialist, Office of the Secretary.

[FR Doc. 2021–28146 Filed 12–22–21; 11:15 am]

BILLING CODE 7590–01–P

PENSION BENEFIT GUARANTY CORPORATION

Submission of Information Collection for OMB Review; Comment Request; Partitions of Eligible Multiemployer Plans

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of request for extension of OMB approval of information collection.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) is requesting that the Office of Management and Budget (OMB) extend approval, under the Paperwork Reduction Act, of a collection of information contained in its regulation on Partitions of Eligible Multiemployer Plans. This notice informs the public of PBGC's request and solicits public comment on the collection of information.

DATES: Comments must be submitted on or before January 26, 2022.

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.

A copy of the request will be posted on PBGC's website at *https://www.pbgc.gov/prac/laws-and-regulation/federal-register-notices-open-for-comment.* It may also be obtained without charge by writing to the Disclosure Division of the Office of the General Counsel of PBGC, 1200 K Street NW, Washington, DC 20005–4026; or, calling 202–229–4040 during normal business hours (TTY users may call the Federal Relay Service toll-free at 800–877–8339 and ask to be connected to 202–229–4040).

FOR FURTHER INFORMATION CONTACT: Melissa Rifkin (*rifkin.melissa@pbgc.gov*), Attorney, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington DC 2005–4026; 202–229–6563. (TTY and TDD users may call the Federal relay service toll-free at 800–877–8339 and ask to be connected to 202–229–6563.)

SUPPLEMENTARY INFORMATION: The Pension Benefit Guaranty Corporation (PBGC) is requesting that the Office of Management and Budget (OMB) extend approval, under the Paperwork Reduction Act, of a collection of information contained in its regulation on Partitions of Eligible Multiemployer Plans (29 CFR part 4233) (OMB control number 1212–0068; expires February 28, 2022). This notice informs the public of PBGC's request and solicits public comment on the collection of information.

Sections 4233(a) and (b) of the Employee Retirement Income Security Act of 1974 (ERISA) allow a plan sponsor of a multiemployer plan to apply to PBGC for a partition of the plan and state the criteria that PBGC uses to determine a plan's eligibility for a partition.

PBGC's regulation on Partitions of Eligible Multiemployer Plans (29 CFR part 4233) sets forth the procedures for applying for a partition, the information required to be included in a partition application, and notices to interested parties of the application.

PBGC needs the information to determine whether a plan is eligible for partition and whether a proposed partition would comply with the statutory conditions required before PBGC may order a partition.

The collection of information under the regulation has been approved by OMB control number 1212–0068 (expires February 28, 2022). On October 18, 2021, PBGC published in the **Federal Register** (at 86 FR 57706) a notice informing the public of its intent to request an extension of this collection of information. No comments were received. PBGC is requesting that OMB extend approval of the collection for three years. 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.

PBGC estimates that each year there will be one application for a partition submitted by a plan sponsor under this regulation. The total estimated annual burden of the collection of information is 13 hours and $45,600.

Issued in Washington, DC.

Stephanie Cibinic,

Deputy Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2021–27990 Filed 12–23–21; 8:45 am]

BILLING CODE 7709–02–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93831; File No. SR–CBOE–2021–075]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Increase Position Limits for Options on the SPDR Gold Trust and iShares Silver Trust

December 20, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934,[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 7, 2021, Cboe Exchange, Inc. filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to increase position limits for options on the SPDR Gold Trust (''GLD'') and iShares Silver Trust (''SLV''). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Position limits are designed to address potential manipulative schemes and adverse market impacts surrounding the use of options, such as disrupting the market in the security underlying the options. While position limits should address and discourage the potential for manipulative schemes and adverse market impact, if such limits are set too low, participation in the options market may be discouraged. The Exchange believes that position limits must therefore be balanced between mitigating concerns of any potential manipulation and the cost of inhibiting potential hedging activity that could be used for legitimate economic purposes.

The Exchange has observed an ongoing increase in demand, for both trading and hedging purposes, in options on GLD and SLV (collectively, the ''Underlying ETFs''). Though the demand for these options appears to have increased, position limits for options on the Underlying ETFs have remained the same. The Exchange believes these unchanged position limits may have impeded, and may continue to impede, trading activity and strategies of investors, such as use of effective hedging vehicles or income generating strategies (*e.g.,* buy-write or put-write), and the ability of Market-Makers to make liquid markets with tighter spreads in these options resulting in the transfer of volume to over-the-counter (''OTC'') markets. OTC transactions occur through bilateral agreements, the terms of which are not publicly disclosed to the marketplace. As such, OTC transactions do not contribute to the price discovery process on a public exchange or other lit markets. Therefore, the Exchange believes that the proposed increases in position limits for options on the Underlying ETFs may enable liquidity providers to provide additional liquidity to the Exchange and other market participants to transfer their liquidity demands from OTC markets to the Exchange. As described in further detail below, the Exchange believes that the continuously increasing market capitalization of the Underlying ETFs, ETF components, as well as the highly liquid markets for each, reduces the concerns for potential market manipulation and/or disruption in the underlying markets upon increasing position limits, while the rising demand for trading options on the Underlying ETFs for legitimate economic purposes compels an increase in position limits.

Proposed Position Limits for Options on the Underlying ETFs

Position limits for options on ETFs are determined pursuant to Rule 8.30 and vary according to the number of outstanding shares and the trading volumes of the underlying equity security (which includes ETFs) over the past six months. Pursuant to Rule 8.30, the largest in capitalization and the most frequently traded stocks and ETFs have an option position limit of 250,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market; and smaller capitalization stocks and ETFs have position limits of 200,000, 75,000, 50,000 or 25,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market. Options on GLD and SLV are currently subject to the standard position limit of 250,000 contracts as set forth in Rule 8.30. Rule 8.30.07 sets forth separate, higher position limits for specific equity options (including options on specific ETFs).[3] The Exchange proposes to amend Rule 8.30.07 to increase the position limits and, as a result, exercise limits, for options on GLD and options on SLV.[4] Specifically, the proposed rule change increases the current position limit of 250,000 contract for options on GLD and SLV to 500,000 contracts.

The Exchange notes that the proposed position limit for options on GLD and SLV are consistent with current position limits for options on various other ETFs including the iShares MSCI Brazil Capped ETF (''EWZ''), iShares 20+ Year Treasury Bond Fund ETF (''TLT''), iShares MSCI Japan ETF (''EWJ''), iShares iBoxx High Yield Corporate Bond Fund (''HYG'') and Financial Select Sector SPDR Fund (''XLF''). The Exchange represents that both of the Underlying ETFs meet the Exchange's initial listing criteria pursuant to Rule 4.3.06(b) and (c), as well as the continued listing criteria in Rule 4.4 (for ETFs).

Composition and Growth Analysis for Underlying ETFs

As stated above, position (and exercise) limits are intended to prevent the establishment of options positions that can be used to or potentially create incentives to manipulate the underlying market so as to benefit options positions. The Securities and Exchange Commission (the ''Commission'') has recognized that these limits are designed to minimize the potential for mini-manipulations and for corners or squeezes of the underlying market, as well as serve to reduce the possibility for disruption of the options market itself, especially in illiquid classes.[5] The Underlying ETFs, as well as the ETF components, are highly liquid and are based on a broad set of highly liquid securities and other reference assets, as demonstrated through the trading statistics presented in this proposal. To support the proposed position limit increases, the Exchange considered the liquidity of the Underlying ETFs, the value of the Underlying ETFs, their components and the relevant marketplace, the share and option volume for the Underlying ETFs, and, where applicable, the availability or comparison of economically equivalent products to options on the Underlying ETFs.

The Exchange has collected the following trading statistics regarding shares of and options on the Underlying ETFs and the values of the Underlying ETFs and their components:

[3] Adjusted option series, in which one option contract in the series represents the delivery of other than 100 shares of the underlying security as a result of a corporate action by the issuer of the security underlying such option series, do not impact the notional value of the underlying security represented by those options. When an underlying security undergoes a corporate action resulting in adjusted series, the Exchange lists new standard option series across all appropriate expiration months the day after the existing series are adjusted. The adjusted series are generally actively traded for a short period of time following adjustment, but orders to open options positions in the underlying security are almost exclusively placed in the new standard option series contracts.

[4] By virtue of [sic] 8.42.02, which is not being amended by this filing, the exercise limits for GLD and SLV options would be similarly increased.

[5] *See* Securities Exchange Act Release No. 67672 (August 15, 2012), 77 FR 50750 (August 22, 2012) (SR–NYSEAmex–2012–29).

Product	ADV [6] (ETF shares) (millions)	ADV (option contracts)	Shares outstanding (millions) [7]	Fund Market cap (USD) (millions) [8]	Share value [9] (USD)
GLD	12.3	257,700	354.30	70,195.7	161.71 (NAV)
SLV	33.1	376,700	619.3	14,228.4	22.57 (NAV)

The Exchange has collected the same trading statistics, where applicable, as above regarding a sample of other ETFs, as well as the current position limits for options on such ETFs pursuant to Rule 8.30.07, to draw comparisons in support of proposed position limit increases for options on the Underlying ETFs (see further discussion below):

Product	ADV (ETF shares) (millions)	ADV (option contracts)	Shares outstanding (millions)	Fund market cap (USD) (millions)	Share value (USD)	Current position limits
EWZ	29.2	139,400	173.8	6,506.8	33.71 (NAV)	500,000
TLT	11.5	111,800	103.7	17,121.3	136.85 (NAV)	500,000
EWJ	8.2	15,500	185.3	13,860.7	69.72 (NAV)	500,000
HYG	30.5	261,600	254.5	24,067.5	86.86 (NAV)	500,000

The Exchange believes that, overall, the liquidity in the shares of the Underlying ETFs and in their overlying options, the larger market capitalizations for each of the Underlying ETFs, and the overall market landscape relevant to each of the Underlying ETFs support the proposal to increase the position limits for each option class. Given the robust liquidity in and value of the Underlying ETFs and their components, the Exchange does not anticipate that the proposed increase in position limits would create significant price movements as the relevant markets are large enough to adequately absorb potential price movements that may be caused by larger trades.

Specifically, the investment objective of GLD (or the ''Trust'') is to track the performance of the price of gold bullion.[10] GLD offers investors an innovative, relatively cost efficient and secure way to access the gold market, without the necessity of taking physical delivery of gold, and to buy and sell that interest through the trading of a security on a regulated stock exchange. The Trust issues SPDR Gold Shares, which represent fractional, undivided beneficial ownership interests in the Trust, the sole assets of which are gold bullion. The spot price for gold is determined by market forces in the 24-hour global unregulated OTC market for gold including spot, forwards, and options and other derivatives, together with exchange-traded futures and options. The Net Asset Value (''NAV'') of the Trust is calculated based on the total ounces of gold owned by the Trust valued at the London Bullion Market Association (''LBMA'') Gold Price PM of that day (plus any cash held by the Trust less accrued expenses).[11] The Exchange has observed that the ADV in GLD shares has increased from approximately 8.7 million shares in 2019 to 12.3 million shares by the end of 2020. Similarly, the ADV in options on GLD has increased from approximately 153,900 option contracts in 2019 to 257,700 option contracts by the end of 2020. The Exchange also notes that in the first quarter of 2021, GLD options experienced an ADV of approximately 395,100 option contracts. Additionally, comparing the statistics shown in the tables above for GLD and the sample of other ETFs with a current position limit of 500,000 contracts, the Exchange notes that the ADV for GLD options (257,700 option contracts) are more, or just as, liquid as that of the ADV for options on EWZ (139,300 option contracts), TLT (111,800 option contracts), EWJ (15,500 option contracts) and HYG (261,600 option contracts), each ETF of which already has a position limit of 500,000 contracts. Additionally, the ADV for GLD shares (12.3 million shares) is more liquid than that of the ADV for shares of TLT (11.5 million shares) and EWJ (8.2 million shares). Also, as indicated in the table above, GLD's market capitalization (approximately $70.2 billion) is higher than all four of the sample ETFs, which currently have a position limit of 500,000 contracts. In addition to this, the Exchange notes that the NAV of GLD is higher than that of the NAV of the four sample ETFs, which is indicative that the total value of its underlying components is generally higher. The Exchange believes that GLD's share and option volume, its market capitalization, and the comparatively high value of its underlying components (as indicated by its NAV, and as discussed in further detail below) are large enough to absorb potential price movements caused by a large trade in GLD.

Like that of GLD and spot gold, SLV seeks to reflect generally the performance of the price of silver and represents a cost-efficient alternative to investments in physical silver for investors not otherwise in a position to participate directly in the market for physical silver. The SLV's NAV is derived from its holdings in silver valued on the basis of the daily LBMA Silver Price.[12] SLV, too, has experienced a significant increase in ADV in shares and options from 2019 through 2020. It grew from approximately 13.6 million shares in 2019 to 33.1 million shares by the end of 2020, and from approximately 118,800 option contracts

[6] Average daily volume (ADV) data for ETF shares and option contracts, as well as for ETF shares and options on the comparative ETFs presented below, are for all of 2020. Additionally, reference to ADV in ETF shares and ETF options, and indexes herein this proposal are for all of calendar year 2020, unless otherwise indicated.

[7] Shares Outstanding and Net Asset Values (''NAV''), as well as for the comparative ETFs presented below, are as of April 5, 2021 for all ETFs.

[8] Fund Market Capitalization data, as well as for the comparative ETFs presented below, are as of January 14, 2021.

[9] *See supra* note 7.

[10] *See* SPDR Gold Shares, available at *https://www.ssga.com/us/en/intermediary/etfs/funds/spdr-gold-shares-gld* (January 11, 2021).

[11] *See* State Street Global Advisors, SPDR Gold Trust GLD, FAQ (July 2020), available at *https://www.ssga.com/library-content/products/fund-docs/etfs/us/tax-documents/gld-faq.pdf.*

[12] *See* iShares Silver Trust, Fact Sheet as of 9/20/2020, available at *https://www.ishares.com/us/literature/fact-sheet/slv-ishares-silver-trust-fund-fact-sheet-en-us.pdf.*

in 2019 to 376,700 option contracts by the end of 2020. The Exchange also notes that SLV options experienced an ADV of approximately 1.1 million option contracts in the first quarter of 2021.[13] Additionally, SLV generally experiences a significantly greater ADV in shares (33.1 million share) and in options (376,700 option contracts) than that of the ADV in shares and options for EWZ (29.2 million shares and 139,300 option contracts), TLT (11.5 million shares and 111,800 option contracts), EWJ (8.2 million shares and 15,500 option contracts) and HYG (30.5 million shares and 261,600 option contracts), and also has a comparable, or higher, market capitalization (approximately $14.2 billion) than EWZ, TLT and EWJ. As per the table above, options on each of these ETFs already have a position limit of 500,000 contracts—the proposed position limit for SLV options. The Exchange believes that SLV share and option volume and its market capitalization are large enough to absorb potential price movements caused by a large trade in SLV.

While the demand for options trading on GLD and SLV has evidently increased, and continues to increase, the position limits have remained the same, which the Exchange believes may be impacting the ability of Trading Permit Holders (''TPHs'') to effectively hedge against exposure to physical gold and silver. For example, a single TPH may manage groups of mutual funds (*i.e.,* a fund complex), each of which may have different growth objectives. If one portfolio manager with a large group of funds has a relatively small exposure to spot gold or spot silver, they may hedge such exposure using GLD options or SLV options, respectively. Though relatively small, this hedge (up to 250,000 option contracts for GLD and for SLV) may utilize the TPH's entire capacity against the position limit. As a result, the TPH's other portfolio managers must look to use alternative vehicles to hedge gold or silver exposure for the funds under their management. The Exchange understands that, unlike GLD or SLV options, most of these alternatives hedging vehicles are not a perfect hedge, which creates liquidity issues and results in increased trading costs. As a result, the Exchange believes that the proposed position limit increases for both GLD and SLV options will allow TPHs to effectively hedge their total gold or silver exposure without having to seek other, less precise hedging vehicles.

Also, as detailed above, while the Exchange believes that the ADV share and option volume for and overall value of GLD and SLV, particularly as compared across other ETF options with position limits currently set at 500,000 contracts, are large enough to absorb potential price movements caused by a large trade in GLD and SLV, the Exchange also recognizes that the spot metal markets underlying SLV and GLD differ from the equities markets underlying EWZ, EWJ, TLT and HYG. However, the Exchange does not believe these differences warrant the position limits for options on GLD and SLV to be half the size of the position limits of these options, nor does it believe that a position limit increase for options on GLD and SLV will have any adverse impact on the underlying spot gold or silver market.[14]

The Exchange reviewed the amount and value of the gold and silver reserves estimated to be held across the globe,[15] as well as the amount and value held in the London vaults, compared with the amount and value of open interest in SLV and GLD options. Currently, the world's reserves hold approximately 1.7 billion troy ounces of gold (a value of approximately $3 trillion) and 16.1 billion troy ounces of silver (a value of approximately $398.7 billion).[16] Reserves in this context is the amount of gold and silver that is ''currently economic'' and could be developed to the point of business needs (*e.g.,* could be refined by accredited LBMA refiners into new London Good Delivery (''LGD'') bars, which is the gold and silver that, respectively, is held on behalf of the GLD and SLV trusts and underly GLD and SLV shares). That is, the amount of gold and silver reserves is notwithstanding the amount of gold and silver already refined and currently in circulation or held by various entities (*e.g.,* international dealers, mining companies, central banks, and financial institutions).[17] Given the constant mining, manufacturing and circulation of gold and silver, the vast number and types of entities that deal in and hold gold and silver across the globe,[18] and the lack of any universal framework for international reporting on or accounting for gold or silver or other central source that tracks and publishes a complete total of available gold and silver, the Exchange has no way of knowing the total amount of LGD gold or silver bars currently available worldwide. While LBMA publishes the gold and silver amounts held in the London vaults[19] in an effort to improve transparency in the precious metals markets, the Exchange notes that, for the same reasons above, it has no way of definitively knowing what portion of the world's total gold and silver is currently held in the London vaults. The London vaults hold[20] approximately 312.1 million troy ounces of gold (a value of approximately $541.8 billion) and 1.2 million troy ounces of silver (a value of approximately $29.1 billion). The Exchange additionally notes that the total global mined silver output is forecasted to grow by approximately 8% from 2020 through 2021 to a total output of approximately 848.5 million troy ounces (approximately $19.1 billion in value),[21] and that total global mined gold output as of June 2021 was 104.4 million troy ounces (approximately $183.6 billion in value).[22]

GLD options have experienced an average daily open interest in 2021[23] of approximately 3 million contracts, which equates to approximately 302.5 million GLD shares[24] (an average daily total NAV[25] of approximately $60 billion). SLV options have experienced an average daily open interest of approximately 6.3 million contracts, which equates to approximately 628.3

[13] While volume in SLV options in the first quarter of 2021 experienced significantly high volume as a result of unusual market conditions, the Exchange believes that the existing possibility of such significant increases supports the proposed position limit increase.

[14] Amendment No. 2 [sic] adds additional support for increasing position limits for options on GLD and SLV by providing data and analysis regarding the sufficient size and capacity of the related spot metals markets to absorb a potential increase in demand of GLD and SLV options and delivery of the underlying.

[15] *See* National Minerals Information Center, Gold Statistics and Information, Mineral Commodity Summaries, Gold (January 2021) available at *https://pubs.usgs.gov/periodicals/mcs2021/mcs2021-gold.pdf; and* Silver Statistics and Information, Mineral Commodity Summaries, Silver (January 2021) available at *https://pubs.usgs.gov/periodicals/mcs2021/mcs2021-silver.pdf.*

[16] One metric ton equals 32,150.7 troy ounces.

[17] The amount of gold and silver reserves is also notwithstanding LGD bars produced by LBMA-accredited refiners from old gold scrap and non-accredited bars.

[18] Many of which, for security reasons, do not publish information regarding their holdings.

[19] The custodians of the GLD and SLV trusts each maintain the respective trust's holdings in the London vaults, among other locations.

[20] As of September 30, 2021.

[21] *See* The Silver Institute, World Silver Survey (April 2021) available at *https://www.silverinstitute.org/wp-content/uploads/2021/04/World-Silver-Survey-2021.pdf.*

[22] *See* World Gold Council, Data, Demand and Supply, Gold mine production (June 16, 2021) available at *https://www.gold.org/goldhub/data/historical-mine-production.*

[23] Year-to-date daily average open interest through September 2021.

[24] One GLD/SLV option contract equals 100 GLD/SLV shares.

[25] Year-to-date daily average GLD share NAV through September 2021 is $168.47.

million SLV shares [26] (an average daily total NAV [27] of approximately $15 billion). Hypothetically, even if every open GLD and SLV option contract was exercised at once to receive delivery of the underlying shares and all such underlying shares were redeemed with the issuer for the respective underlying physical metal, by taking the average daily total NAV of the ETF shares equivalent to the average daily open interest in GLD and SLV options over the spot price of gold ($1736.04) and silver ($24.80),[28] the Exchange estimates that redemption of all of the ETF shares (equivalent to the average daily open interest in GLD and SLV options) would correspond to delivery of approximately 29.4 million troy ounces of gold and 603.9 million troy ounces of silver—that is, only approximately 1.7% and 3.8% of the total gold and silver reserves, respectively, and approximately 9.4% and 51.5% of the gold and silver holdings, respectively, in the London vaults. As such, even if this hypothetical, unlikely event occurred, it would impact only a negligible portion of the world's gold and silver reserves, a fraction of the gold stored in the London vaults, and, in an extreme worst-case scenario, half of the silver in the London vaults; which, as stated, does not account for the total amount of LGD bars available globally nor the amount of reserves readily at hand to refine into LGD bars. The Exchange understands that market participants by and large use GLD and SLV options to hold a leveraged position in the market, taking a view of market performance over a defined period of time, or use such options to hedge or reduce the risk exposure of their portfolios, as described above. As such, most positions in GLD and SLV options are not intended to be exercised to receive delivery of the underlying shares, but instead, are closed out or rolled. The Exchange also notes that most of the activity in the underlying GLD and SLV shares takes place on the secondary market (*e.g.,* on an exchange), as opposed to the primary market (*i.e.,* ETF creations and redemptions). The Exchange believes that, given the typical use cases for GLD and SLV options, an increase in the position limits for GLD and SLV options would cause a de minimis increase, if any, in delivery or in creations and redemptions of shares in the underlying ETFs. As a result of the above-described review of the average daily open options interest compared to the world's metal reserves and the holdings in the London vaults, as well as the global mined gold and silver output, coupled with the understanding that the principal use cases for taking positions in the GLD and SLV options markets do not involve taking delivery of the underlying, the Exchange believes that the current supply of spot gold and silver is more than adequate to meet a potential increase in demand and delivery of GLD's and SLV's underlying metals components as a result of position limit increases for options on GLD and SLV.

Indeed, the gold and silver markets have proven resilient in the face of actual, extraordinary economic and market events that have resulted in an increase in demand for physical gold and silver and in holdings of such metal-based products. For example, beginning in March 2020, interest in gold and silver significantly increased as a result of the COVID–19 pandemic, and gold and silver price momentum continued through the year, peaking in August 2020.[29] Gold-backed exchange-traded products (''ETPs'') accounted for almost two-thirds of total gold-related investment demand during the first three quarters of 2020,[30] and inflows into silver-backed ETPs over the first three quarters of 2020 nearly tripled the amount of inflow over the same period of time in 2019.[31] In particular, GLD experienced an inflow of approximately $15.4 billion in assets (or approximately 7.3 million troy ounces) in 2020; a 35% increase in AUM from 2019, and SLV experienced an inflow of approximately $8.3 billion in assets (or approximately 196 million troy ounces) in 2020; a 126% increase in AUM from 2019. Open interest in GLD options from the onset of the pandemic in March 2020 was approximately 3.7 million contracts and in SLV options was approximately 4.2 million contracts, and in August 2020, when prices peaked, open interest in GLD options was approximately 4.9 million contracts and in SLV options was approximately 8.2 million contracts. Additionally, in late January and into early February 2021, silver-backed inflows increased again, triggered by comments coordinated across social media platforms in an attempt to push silver higher, and silver-backed ETP holdings (including in SLV) jumped by almost 120 million troy ounces [32] and open interest in SLV options was approximately 6.7 million contracts.

From March 2020 through August 2020, the amount of LGD bars held in the London vaults averaged approximately 278.1 million troy ounces in gold and approximately 1.13 billion troy ounces in silver month-to-month. For the immediately preceding six-month period (September 2019 through February 2020), the average monthly amount of gold held in the London vaults was approximately 267.3 million troy ounces and the average monthly amount of silver held was 1.16 billion troy ounces, thus demonstrating that, faced with such a significant increase in demand for gold, silver and related products as experienced during the onset and more economically turbulent period of the COVID–19 pandemic and as demonstrated by the inflows into GLD and SLV, the London vaults experienced no reduction in its gold holdings (in fact, the average month vault holdings increased) and only a marginal reduction in its silver holdings. Likewise, across January and February 2021, the silver holdings in the London vaults averaged 1.11 billion troy ounces, while over the two months prior to this time frame the London vaults averaged 1.08 billion troy ounces. As such, the Exchange believes that an increase in gold and silver ETP and options holdings does not necessarily impact physical gold and silver supplies and that such supplies have sufficient capacity to meet potential increases in demand for gold- and silver-related products, including GLD and SLV options.

The Exchange also reviewed the gold and silver futures markets, the volume and value of which the Exchange believes indicate sufficient size and liquidity in the underlying markets to absorb potential price movements and large-sized trades as a result of position limit increases for options on GLD and SLV. The Exchange notes that gold futures currently have a value of approximately $93.2 billion in open interest and have experienced an ADV of approximately 264,000 contracts (equivalent to approximately 264 million GLD contracts) in 2021 to

[26] *See supra* note 22.

[27] Year-to-date daily average GLD share NAV through September 2021 is $23.84.

[28] Spot prices as of October 3, 2021.

[29] *See* World Gold Council, Global gold-backed ETF flows, Full Year 2020 (January 13, 2021) available at *https://www.gold.org/goldhub/data/global-gold-backed-etf-holdings-and-flows/2020/december; and supra* note 24 [sic] at 8.

[30] *See* World Gold Council, Global gold-backed ETF flows, Full Year 2020 (January 13, 2021) available at *https://www.gold.org/goldhub/data/global-gold-backed-etf-holdings-and-flows/2020/december.*

[31] *See* The Silver Institute, Inflows into silver-backed exchange-traded products nearly triple year-on-year over the first three quarters of 2020 (October 15, 2020) available at *https://www.silverinstitute.org/inflows-silver-backed-exchange-traded-products-nearly-triple-year-year-first-three-quarters-2020/.*

[32] *See supra* note 24 [sic] at 22.

date.[33] Also, gold futures are currently subject to a position limit of 6,000 contracts, which is notionally equivalent to 6,000,000 GLD contracts. Additionally, the Exchange understands that its Market-Makers use both GLD and gold futures to hedge their GLD options positions, which the Exchange believes provides for a balance across the gold-related marketplaces, mitigating potential concern that either the underlying or the futures market might experience additional pressure as a result of an increase in activity in the GLD options space. Likewise, the Exchange notes that silver futures currently have a value of approximately $25.7 billion in open interest, have experienced an ADV of approximately 93,000 contracts (equivalent to approximately 465 million SLV contracts) in 2021 to date,[34] and are currently subject to a position limit of 3,000 contracts, which is notionally equivalent to 15,000,000 SLV contracts. The Exchange believes the robust volume in and value of the gold and silver futures markets indicates that the underlying markets are sufficiently large and liquid enough to absorb potential price movements and large-sized trades as a result of position limit increases for options on GLD and SLV.

Additionally, the Exchange reviewed the volume-weighted average of the absolute value [35] of deltas for GLD and SLV options trades over approximately the last two years (from March 2019 through June 2021). Essentially, the delta compares the relationship between the change in the price of an underlying and of an option. Absolute delta value ranges from 0 to 1. The lower the absolute delta value, the less the option price is sensitive to changes in the price of the underlying (*i.e.,* delta exposure). Conversely, the higher the absolute delta value, the more the option price will change given a change in the underlying price. The Exchange believes that volume-weighted average delta over time is indicative as to whether an underlying market is large enough to absorb increased activity in the related options markets. That is, the more delta exposure per trade, the more options exposure there is that necessitates a hedge trade in the underlying, which may, in turn, potentially increase the impact on the underlying markets. Review of the volume-weighted average delta in connection with GLD and SLV options over the last two years showed that the average absolute delta per trade for GLD options trades was approximately 0.34 and for SLV options trades was approximately 0.28. The Exchange notes that both averages indicate relatively minimal amounts of average delta exposure and, thus, minimal amounts of GLD and SLV options exposure need to be hedged, on average. As a result, the Exchange believes that increases in GLD and SLV options trading would have minimal impact on the ability of the underlying metals markets to absorb any additional volume related to increased position limits and hedging activity.

Creation and Redemption for ETFs

The Exchange believes that the creation and redemption process for the Underlying ETFs lessens the potential for manipulative activity with options on the Underlying ETFs. When an ETF provider wants to create more shares, it looks to an Authorized Participant (''AP'') (generally a market maker or other large financial institution) to acquire the underlying components the ETF is to hold. For instance, when an ETF is designed to track the performance of an index, the AP can purchase all the constituent securities in the exact same weight as the index, then deliver those shares to the ETF provider. In exchange, the ETF provider gives the AP a block of equally valued ETF shares, on a one-for-one fair value basis. The price is based on the NAV, not the market value at which the ETF is trading. The creation of new ETF units can be conducted during an entire trading day and is not subject to position limits. This process works in reverse where the ETF provider seeks to decrease the number of shares that are available to trade. The creation and redemption processes for the Underlying ETFs creates a direct link to the underlying components of the ETF and serves to mitigate potential price impact of the ETF shares that might otherwise result from increased position limits for the options on the Underlying ETFs.

The Exchange understands that the ETF creation and redemption processes seek to keep an ETF's share price trading in line with the product's underlying net asset value. Because an ETF trades like a stock, its share price will fluctuate during the trading day, due to simple supply and demand. If demand to buy an ETF is high, for instance, an ETF's share price might rise above the value of its underlying components. When this happens, the AP or issuer believes the ETF may now be overpriced, so it may buy shares of the component assets and then sell ETF shares in the open market. This may drive the ETF's share price back toward the underlying net asset value. Likewise, if an ETF share price starts trading at a discount to the component assets it holds, the AP or issuer can buy shares of the ETF and redeem them for the underlying components. Buying undervalued ETF shares may drive the share price of an ETF back toward fair value. This arbitrage process helps to keep an ETF's share price in line with the value of its underlying portfolio.

Surveillance and Reporting Requirements

The Exchange believes that increasing the position limits for the options on the Underlying ETFs would lead to a more liquid and competitive market environment for these options, which will benefit customers interested in trading these products. The reporting requirement for the options on the Underlying ETFs would remain unchanged. Thus, the Exchange would still require that each TPH or TPH organization that maintains positions in the options on the same side of the market, for its own account or for the account of a customer, report certain information to the Exchange. This information would include, but would not be limited to, the options' positions, whether such positions are hedged and, if so, a description of the hedge(s). Market-Makers [36] (including Designated Primary Market-Makers (''DPMs'')) [37] would continue to be exempt from this reporting requirement, however, the Exchange may access Market-Maker position information.[38] Moreover, the Exchange's requirement that TPHs file reports with the Exchange for any customer who held aggregate large long or short positions on the same side of the market of 200 or more option contracts of any single class for the

[33] Year-to-date ADV through May 2021.

[34] *See id.*

[35] Put deltas are always negative, therefore, absolute value is used to view the average delta across calls and puts.

[36] A Market-Maker [sic] ''Trading Permit Holder registered with the Exchange pursuant to Rule 3.52 for the purpose of making markets in option contracts traded on the Exchange and that has the rights and responsibilities set forth in Chapter 5, Section D of the Rules.'' *See* Rule 1.1.

[37] A Designated Primary Market-Maker ''is TPH organization that is approved by the Exchange to function in allocated securities as a Market-Maker (as defined in Rule 8.1) and is subject to the obligations under Rule 5.54 or as otherwise provided under the rules of the Exchange.'' *See* Rule 1.1.

[38] The Options Clearing Corporation (''OCC'') through the Large option Position Reporting (''LOPR'') system acts as a centralized service provider for TPH compliance with position reporting requirements by collecting data from each TPH or TPH organization, consolidating the information, and ultimately providing detailed listings of each TPH's report to the Exchange, as well as Financial Industry Regulatory Authority, Inc. (''FINRA''), acting as its agent pursuant to a regulatory services agreement (''RSA'').

previous day will remain at this level for the options subject to this proposal and will continue to serve as an important part of the Exchange's surveillance efforts.[39]

The Exchange believes that the existing surveillance procedures and reporting requirements at the Exchange and other SROs are capable of properly identifying disruptive and/or manipulative trading activity. The Exchange also represents that it has adequate surveillances in place to detect potential manipulation, as well as reviews in place to identify potential changes in composition of the Underlying ETFs and continued compliance with the Exchange's listing standards. These procedures utilize daily monitoring of market activity via automated surveillance techniques to identify unusual activity in both options and the underlyings, as applicable.[40] The Exchange also notes that large stock holdings must be disclosed to the Commission by way of Schedules 13D or 13G,[41] which are used to report ownership of stock which exceeds 5% of a company's total stock issue and may assist in providing information in monitoring for any potential manipulative schemes.

The Exchange believes that the current financial requirements imposed by the Exchange and by the Commission adequately address concerns regarding potentially large, unhedged positions in the options on the Underlying ETFs. Current margin and risk-based haircut methodologies serve to limit the size of positions maintained by any one account by increasing the margin and/or capital that a TPH must maintain for a large position held by itself or by its customer.[42] In addition, Rule 15c3–1[43] imposes a capital charge on TPHs to the extent of any margin deficiency resulting from the higher margin requirement.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[44] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[45] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[46] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed increase in position limits for options on GLD and SLV will remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest, because it will provide market participants with the ability to more effectively execute their trading and hedging activities. The proposed increases will allow market participants to more fully implement hedging strategies in related derivative products and to further use options to achieve investment strategies (*e.g.,* there are other ETPs that use options on GLD and SLV as part of their investment strategy, and the applicable position limits as they stand today may inhibit these other ETPs in achieving their investment objectives, to the detriment of investors). Also, increasing the applicable position limits may allow Market-Makers to provide the markets for these options with more liquidity in amounts commensurate with increased consumer demand in such markets. The proposed position limit increases may also encourage other liquidity providers to shift liquidity, as well as encourage consumers to shift demand, from OTC markets onto the Exchange, which will enhance the process of price discovery conducted on the Exchange through increased order flow.

In addition, the Exchange believes that the structure of the Underlying ETFs, the considerable market capitalization of the funds, capacity of the underlying component assets, and liquidity of the markets for the applicable options and underlying shares will mitigate concerns regarding potential manipulation of the products and/or disruption of the underlying markets upon increasing the relevant position limits. As a general principle, increases in market capitalizations, active trading volume, and deep liquidity of the underlying markets do not lead to manipulation and/or disruption. This general principle applies to the recently observed increased levels of market capitalization and trading volume and liquidity in shares of and options on the Underlying ETFs (as described above). As a result, the Exchange does not believe that the options markets or underlying markets would become susceptible to manipulation and/or disruption as a result of the proposed position limit increases. Indeed, the Commission has previously expressed the belief that not just increasing, but removing, position and exercise limits may bring additional depth and liquidity to the options markets without increasing concerns regarding intermarket manipulation or disruption of the options or the underlying securities.[47]

Further, the Exchange notes that the proposed rule change to increase position limits for select actively traded options is not novel and the Commission has approved similar proposed rule changes by the Exchange to increase position limits for options on similar, highly liquid and actively traded ETPs.[48] Furthermore, the Exchange again notes that that the proposed position limits for options on GLD and SLV are consistent with existing position limits for options on other ETFs in Rule 8.30.07, including options on ETFs that experience similar, or even less, volume than GLD and SLV options, as demonstrated above.

The Exchange's surveillance and reporting safeguards continue to be designed to deter and detect possible manipulative behavior that might arise from increasing or eliminating position and exercise limits in certain classes. The Exchange believes that the current financial requirements imposed by the Exchange and by the Commission adequately address concerns regarding potentially large, unhedged position in the options on the Underlying ETFs, further promoting just and equitable principles of trading, the maintenance of a fair and orderly market, and the protection of investors.

[39] *See* Rule 8.43 for reporting requirements.

[40] The Exchange believes these procedures have been effective for the surveillance of trading the options subject to this proposal and will continue to employ them.

[41] 17 CFR 240.13d–1.

[42] *See* Rule 10.3 for a description of margin requirements.

[43] 17 CFR 240.15c3–1.

[44] 15 U.S.C. 78f(b).

[45] 15 U.S.C. 78f(b)(5).

[46] *Id.*

[47] *See* Securities Exchange Act Release No. 62147 [sic] (October 28 [sic], 2005) (SR–CBOE–2005–41), at 62149.

[48] *See* Securities Exchange Act Release Nos. 88768 (April 29, 2020), 85 FR 26736 (May 5, 2020) (SR–CBOE–2020–015); 83415 (June 12, 2018), 83 FR 28274 (June 18, 2018) (SR–CBOE–2018–042); *and* 68086 (October 23, 2012), 77 FR 65600 (October 29, 2012) (SR–CBOE–2012–066).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the increased position limits (and exercise limits) will be available to all market participants and apply to each in the same manner. The Exchange believes that the proposed rule change will provide additional opportunities for market participants to more efficiently achieve their investment and trading objectives of market participants. The proposed rule change would also align the position limits for GLD and SLV options with the position limits for other ETF options, which, as demonstrated herein, experience similar, or even less, volume than options on GLD and SLV.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the Act. On the contrary, the Exchange believes the proposal promotes competition because it may attract additional order flow from the OTC market to exchanges, which would in turn compete amongst each other for those orders.[49] The Exchange believes market participants would benefit from being able to trade options with increased position limits in an exchange environment in several ways, including but not limited to the following: (1) Enhanced efficiency in initiating and closing out position; (2) increased market transparency; and (3) heightened contra-party creditworthiness due to the role of OCC as issuer and guarantor. The Exchange notes that other options exchanges may choose to file similar proposals with the Commission to increase position limits on options on the Underlying ETFs.

[49] Additionally, several other options exchanges have the same position limits as the Exchange, as they incorporate by reference to the Exchange's position limits, and as a result the position limits for options on the Underlying ETFs will increase at those exchanges. For example, Nasdaq Options position limits are determined by the position limits established by the Exchange. *See* Nasdaq Stock Market LLC Rules, Options 9, Sec. 13 (Position Limits).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. by order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2021–075 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2021–075. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2021–075 and should be submitted on or before January 18, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[50]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2021–27924 Filed 12–23–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93822; File No. SR–CboeBZX–2021–051]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing of Amendment No. 1 to a Proposed Rule Change To List and Trade Shares of the ARK 21Shares Bitcoin ETF Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares

December 17, 2021.

I. Introduction

On July 20, 2021, Cboe BZX Exchange, Inc. (''BZX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the ARK 21Shares Bitcoin ETF under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares. The proposed rule change was published for comment in the **Federal Register** on August 6, 2021.[3]

[50] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 92543 (Aug. 2, 2021), 86 FR 43289. Comments on the proposed rule change can be found at: *https://www.sec.gov/comments/sr-cboebzx-2021-051/srcboebzx2021051.htm.*

On September 15, 2021, pursuant to Section 19(b)(2) of the Exchange Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On November 2, 2021, the Commission instituted proceedings under Section 19(b)(2)(B) of the Exchange Act[6] to determine whether to approve or disapprove the proposed rule change.[7]

On December 9, 2021, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the proposed rule change as originally filed.[8] The Commission is publishing this notice to solicit comments from interested persons on Amendment No. 1, as described in Items II and III below, which Items have been prepared by the Exchange.

II. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes a rule change to list and trade shares of the ARK 21Shares Bitcoin ETF (the ''Trust''),[9] under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares. The shares of the Trust are referred to herein as the ''Shares.''

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

III. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

This Amendment No. 1 to SR–CboeBZX–2021–051 amends and replaces in its entirety the proposal as originally submitted on July 20, 2021. The Exchange submits this Amendment No. 1 in order to clarify certain points and add additional details to the proposal.

The Exchange proposes to list and trade the Shares under BZX Rule 14.11(e)(4),[10] which governs the listing and trading of Commodity-Based Trust Shares on the Exchange.[11] 21Shares US LLC is the sponsor of the Trust (the ''Sponsor''). The Shares will be registered with the Commission by means of the Trust's registration statement on Form S–1 (the ''Registration Statement'').[12] As further discussed below, the Commission has historically approved or disapproved exchange filings to list and trade series of Trust Issued Receipts, including spot-based Commodity-Based Trust Shares, on the basis of whether the listing exchange has in place a comprehensive surveillance sharing agreement with a regulated market of significant size related to the underlying commodity.[13] A survey of previously approved series of Commodity-Based Trust Shares and Currency Trust Shares makes clear that the spot markets for commodities and currencies held in such ETPs are generally unregulated. In fact, the Commission specifically noted in the Winklevoss Order that the first gold ETP approval order, which was also the first commodity-trust ETP, ''was based on an assumption that the currency market and the spot gold market were largely unregulated.''[14] This makes clear that the applicable standard is not whether the underlying commodity market itself is regulated. Further to this point, prior orders have also emphasized that in every prior approval order for Commodity-Based Trust Shares there was a regulated derivatives market of significant size, generally a Commodity Futures Trading Commission (the ''CFTC'') regulated futures market.[15]

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 92989, 86 FR 52530 (Sept. 21, 2021).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 93510, 86 FR 61820 (Nov. 8, 2021).

[8] Amendment No. 1 is available at: *https://www.sec.gov/comments/sr-cboebzx-2021-051/srcboebzx2021051-9436437-263630.pdf.*

[9] The Trust was formed as a Delaware statutory trust on June 22, 2021 and is operated as a grantor trust for U.S. federal tax purposes. The Trust has no fixed termination date.

[10] The Commission approved BZX Rule 14.11(e)(4) in Securities Exchange Act Release No. 65225 (August 30, 2011), 76 FR 55148 (September 6, 2011) (SR–BATS–2011–018).

[11] All statements and representations made in this filing regarding (a) the description of the portfolio, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange rules and surveillance procedures shall constitute continued listing requirements for listing the Shares on the Exchange.

[12] *See* draft Registration Statement on Form S–1, dated June 28, 2021 submitted to the Commission by the Sponsor on behalf of the Trust. The descriptions of the Trust, the Shares, and the Index (as defined below) contained herein are based, in part, on information in the Registration Statement. The Registration Statement is not yet effective and the Shares will not trade on the Exchange until such time that the Registration Statement is effective.

[13] *See* Securities Exchange Act Release No. 83723 (July 26, 2018), 83 FR 37579 (August 1, 2018). This proposal was subsequently disapproved by the Commission. *See* Securities Exchange Act Release No. 83723 (July 26, 2018), 83 FR 37579 (August 1, 2018) (the ''Winklevoss Order'').

[14] *See* Winklevoss Order at 37592 and Exchange Act Release No. 50603 (Oct. 28, 2004), 69 FR 64614 (Nov. 5, 2004) (SR–NYSE–2004–22) (order approving the listing and trading of streetTRACKS Gold Shares) (the ''First Gold Approval Order'').

[15] *See* Winklevoss Order at 37592. *See also* the First Gold Approval Order at 64618–19; iShares COMEX Gold Trust, Exchange Act Release No. 51058 (Jan. 19, 2005), 70 FR 3749, 3751, 3754–55 (Jan. 26, 2005) (SR–Amex–2004–38); iShares Silver Trust, Exchange Act Release No. 53521 (Mar. 20, 2006), 71 FR 14967, 14968, 14973–74 (Mar. 24, 2006) (SR–Amex–2005–072); ETFS Gold Trust, Exchange Act Release No. 59895 (May 8, 2009), 74 FR 22993, 22994–95, 22998, 23000 (May 15, 2009) (SR–NYSEArca–2009–40); ETFS Silver Trust, Exchange Act Release No. 59781 (Apr. 17, 2009), 74 FR 18771, 18772, 18775–77 (Apr. 24, 2009) (SR–NYSEArca–2009–28); ETFS Palladium Trust, Exchange Act Release No. 61220 (Dec. 22, 2009), 74 FR 68895, 68896 (Dec. 29, 2009) (SR–NYSEArca–2009–94) (notice of proposed rule change included NYSE Arca's representation that ''[t]he most significant palladium futures exchanges are the NYMEX and the Tokyo Commodity Exchange,'' that ''NYMEX is the largest exchange in the world for trading precious metals futures and options,'' and that NYSE Arca ''may obtain trading information via the Intermarket Surveillance Group,'' of which NYMEX is a member, Exchange Act Release No. 60971 (Nov. 9, 2009), 74 FR 59283, 59285–86, 59291 (Nov. 17, 2009)); ETFS Platinum Trust, Exchange Act Release No. 61219 (Dec. 22, 2009), 74 FR 68886, 68887–88 (Dec. 29, 2009) (SR–NYSEArca–2009–95) (notice of proposed rule change included NYSE Arca's representation that ''[t]he most significant platinum futures exchanges are the NYMEX and the Tokyo Commodity Exchange,'' that ''NYMEX is the largest exchange in the world for trading precious metals futures and options,'' and that NYSE Arca ''may obtain trading information via the Intermarket Surveillance Group,'' of which NYMEX is a member, Exchange Act Release No. 60970 (Nov. 9, 2009), 74 FR 59319, 59321, 59327 (Nov. 17, 2009)); Sprott Physical Gold Trust, Exchange Act Release No. 61496 (Feb. 4, 2010), 75 FR 6758, 6760 (Feb. 10, 2010) (SR–NYSEArca–2009–113) (notice of proposed rule change included NYSE Arca's representation that the COMEX is one of the ''major world gold markets,'' that NYSE Arca ''may obtain trading information via the Intermarket Surveillance Group,'' and that NYMEX, of which COMEX is a division, is a member of the Intermarket Surveillance Group, Exchange Act Release No. 61236 (Dec. 23, 2009), 75 FR 170, 171, 174 (Jan. 4, 2010)); Sprott Physical Silver Trust, Exchange Act Release No. 63043 (Oct. 5, 2010), 75 FR 62615, 62616, 62619, 62621 (Oct. 12, 2010) (SR–NYSEArca–2010–84); ETFS Precious Metals Basket Trust, Exchange Act Release No. 62692 (Aug. 11, 2010), 75 FR 50789, 50790 (Aug. 17, 2010) (SR–NYSEArca–2010–56) (notice of proposed rule change included NYSE Arca's representation that

Continued

''the most significant gold, silver, platinum and palladium futures exchanges are the COMEX and the TOCOM'' and that NYSE Arca ''may obtain trading information via the Intermarket Surveillance Group,'' of which COMEX is a member, Exchange Act Release No. 62402 (Jun. 29, 2010), 75 FR 39292, 39295, 39298 (July 8, 2010)); ETFS White Metals Basket Trust, Exchange Act Release No. 62875 (Sept. 9, 2010), 75 FR 56156, 56158 (Sept. 15, 2010) (SR–NYSEArca–2010–71) (notice of proposed rule change included NYSE Arca's representation that ''the most significant silver, platinum and palladium futures exchanges are the COMEX and the TOCOM'' and that NYSE Arca ''may obtain trading information via the Intermarket Surveillance Group,'' of which COMEX is a member, Exchange Act Release No. 62620 (July 30, 2010), 75 FR 47655, 47657, 47660 (Aug. 6, 2010)); ETFS Asian Gold Trust, Exchange Act Release No. 63464 (Dec. 8, 2010), 75 FR 77926, 77928 (Dec. 14, 2010) (SR–NYSEArca–2010–95) (notice of proposed rule change included NYSE Arca's representation that ''the most significant gold futures exchanges are the COMEX and the Tokyo Commodity Exchange,'' that ''COMEX is the largest exchange in the world for trading precious metals futures and options,'' and that NYSE Arca ''may obtain trading information via the Intermarket Surveillance Group,'' of which COMEX is a member, Exchange Act Release No. 63267 (Nov. 8, 2010), 75 FR 69494, 69496, 69500–01 (Nov. 12, 2010)); Sprott Physical Platinum and Palladium Trust, Exchange Act Release No. 68430 (Dec. 13, 2012), 77 FR 75239, 75240–41 (Dec. 19, 2012) (SR–NYSEArca–2012–111) (notice of proposed rule change included NYSE Arca's representation that ''[f]utures on platinum and palladium are traded on two major exchanges: The New York Mercantile Exchange . . . and Tokyo Commodities Exchange'' and that NYSE Arca ''may obtain trading information via the Intermarket Surveillance Group,'' of which COMEX is a member, Exchange Act Release No. 68101 (Oct. 24, 2012), 77 FR 65732, 65733, 65739 (Oct. 30, 2012)); APMEX Physical—1 oz. Gold Redeemable Trust, Exchange Act Release No. 66930 (May 7, 2012), 77 FR 27817, 27818 (May 11, 2012) (SR–NYSEArca–2012–18) (notice of proposed rule change included NYSE Arca's representation that NYSE Arca ''may obtain trading information via the Intermarket Surveillance Group,'' of which COMEX is a member, and that gold futures are traded on COMEX and the Tokyo Commodity Exchange, with a cross-reference to the proposed rule change to list and trade shares of the ETFS Gold Trust, in which NYSE Arca represented that COMEX is one of the ''major world gold markets,'' Exchange Act Release No. 66627 (Mar. 20, 2012), 77 FR 17539, 17542–43, 17547 (Mar. 26, 2012)); JPM XF Physical Copper Trust, Exchange Act Release No. 68440 (Dec. 14, 2012), 77 FR 75468, 75469–70, 75472, 75485–86 (Dec. 20, 2012) (SR–NYSEArca–2012–28); iShares Copper Trust, Exchange Act Release No. 68973 (Feb. 22, 2013), 78 FR 13726, 13727, 13729–30, 13739–40 (Feb. 28, 2013) (SR–NYSEArca–2012–66); First Trust Gold Trust, Exchange Act Release No. 70195 (Aug. 14, 2013), 78 FR 51239, 51240 (Aug. 20, 2013) (SR–NYSEArca–2013–61) (notice of proposed rule change included NYSE Arca's representation that FINRA, on behalf of the exchange, may obtain trading information regarding gold futures and options on gold futures from members of the Intermarket Surveillance Group, including COMEX, or from markets ''with which [NYSE Arca] has in place a comprehensive surveillance sharing agreement,'' and that gold futures are traded on COMEX and the Tokyo Commodity Exchange, with a cross-reference to the proposed rule change to list and trade shares of the ETFS Gold Trust, in which NYSE Arca represented that COMEX is one of the ''major world gold markets,'' Exchange Act Release No. 69847 (June 25, 2013), 78 FR 39399, 39400, 39405 (July 1, 2013)); Merk Gold Trust, Exchange Act Release No. 71378 (Jan. 23, 2014), 79 FR 4786, 4786–87 (Jan. 29, 2014) (SR–NYSEArca–2013–137) (notice of proposed rule change included NYSE Arca's representation that ''COMEX is the largest gold futures and options exchange'' and that NYSE Arca ''may obtain trading information via the Intermarket Surveillance Group,'' including with respect to transactions occurring on COMEX pursuant to CME and NYMEX's membership, or from exchanges ''with which [NYSE Arca] has in place a comprehensive surveillance sharing agreement,'' Exchange Act Release No. 71038 (Dec. 11, 2013), 78 FR 76367, 76369, 76374 (Dec. 17, 2013)); Long Dollar Gold Trust, Exchange Act Release No. 79518 (Dec. 9, 2016), 81 FR 90876, 90881, 90886, 90888 (Dec. 15, 2016) (SR–NYSEArca–2016–84).

[16] *Id.*

Despite the lack of regulation of the underlying spot commodity and currency markets, the Commission approved series of Currency and Commodity-Based Trust Shares, including those that held gold, silver, platinum, palladium, copper, and other commodities and currencies, because it determined that the futures markets for these commodities and currencies represented regulated markets of significant size and that the listing exchange had a surveillance sharing agreement in place with that market.[16]

The Exchange acknowledges that unregulated currency and commodity markets do not provide the same protections as the markets that are subject to the Commission's oversight. However, the Commission has consistently looked to surveillance sharing agreements with an underlying futures market to determine whether ETPs holding currency or commodities were consistent with the Act, as established above. As such, the Commission's regulated market of significant size test does not require that the spot bitcoin market be regulated to approve this proposal. To the contrary, precedent makes clear that any requirement that the spot bitcoin market be a ''regulated market'' prior to approval would be incongruous with all prior spot commodity and currency approval orders. With this in mind, the CME Bitcoin Futures market is the proper market for the Commission to consider in determining whether this proposal is consistent with the Act. The Exchange has a comprehensive surveillance sharing agreement in place with CME, which operates a bitcoin futures market that, as established by the included analysis below, represents a regulated market of significant size related to the underlying commodity (bitcoin) to be held by the Trust. Therefore, both the Exchange and the Sponsor believe that the CME Bitcoin Futures market satisfies the standard that the Commission has applied to all previously approved series of Commodity-Based Trust Shares and that this proposal should be approved.

Background

Bitcoin is a digital asset based on the decentralized, open source protocol of the peer-to-peer computer network launched in 2009 that governs the creation, movement, and ownership of bitcoin and hosts the public ledger, or ''blockchain,'' on which all bitcoin transactions are recorded (the ''Bitcoin Network'' or ''Bitcoin''). The decentralized nature of the Bitcoin Network allows parties to transact directly with one another based on cryptographic proof instead of relying on a trusted third party. The protocol also lays out the rate of issuance of new bitcoin within the Bitcoin Network, a rate that is reduced by half approximately every four years with an eventual hard cap of 21 million. It's generally understood that the combination of these two features—a systemic hard cap of 21 million bitcoin and the ability to transact trustlessly with anyone connected to the Bitcoin Network—gives bitcoin its value.[17] The first rule filing proposing to list an exchange-traded product to provide exposure to bitcoin in the U.S. was submitted by the Exchange on June 30, 2016.[18] At that time, blockchain technology, and digital assets that utilized it, were relatively new to the broader public. The market cap of all bitcoin in existence at that time was approximately $10 billion. No registered offering of digital asset securities or shares in an investment vehicle with exposure to bitcoin or any other cryptocurrency had yet been conducted, and the regulated infrastructure for conducting a digital asset securities offering had not begun to develop.[19] Similarly, regulated U.S. bitcoin futures contracts did not exist. The CFTC had determined that bitcoin is a commodity,[20] but had not engaged in

[17] For additional information about bitcoin and the Bitcoin Network, *see https://bitcoin.org/en/getting-started; https://www.fidelitydigitalassets.com/articles/addressing-bitcoin-criticisms;* and *https://www.vaneck.com/education/investment-ideas/investing-in-bitcoin-and-digital-assets/.*

[18] *See* Winklevoss Order.

[19] Digital assets that are securities under U.S. law are referred to throughout this proposal as ''digital asset securities.'' All other digital assets, including bitcoin, are referred to interchangeably as ''cryptocurrencies'' or ''virtual currencies.'' The term ''digital assets'' refers to all digital assets, including both digital asset securities and cryptocurrencies, together.

[20] *See* ''In the Matter of Coinflip, Inc.'' (''Coinflip'') (CFTC Docket 15–29 (September 17, 2015)) (order instituting proceedings pursuant to Sections 6(c) and 6(d) of the CEA, making findings and imposing remedial sanctions), in which the CFTC stated: ''Section 1a(9) of the CEA defines

significant enforcement actions in the space. The New York Department of Financial Services (''NYDFS'') adopted its final BitLicense regulatory framework in 2015, but had only approved four entities to engage in activities relating to virtual currencies (whether through granting a BitLicense or a limited-purpose trust charter) as of June 30, 2016.[21] While the first over-the-counter bitcoin fund launched in 2013, public trading was limited and the fund had only $60 million in assets.[22] There were very few, if any, traditional financial institutions engaged in the space, whether through investment or providing services to digital asset companies. In January 2018, the Staff of the Commission noted in a letter to the Investment Company Institute and SIFMA that it was not aware, at that time, of a single custodian providing fund custodial services for digital assets.[23] Fast forward to the fourth quarter of 2021 and the digital assets financial ecosystem, including bitcoin, has progressed significantly. The development of a regulated market for digital asset securities has significantly evolved, with market participants having conducted registered public offerings of both digital asset securities [24] and shares in investment vehicles holding bitcoin futures.[25] Additionally, licensed and regulated service providers have emerged to provide fund custodial services for digital assets, among other services. For example, in May 2021, the Staff of the Commission released a statement permitting open-end mutual funds to invest in cash-settled bitcoin futures; in December 2020, the Commission adopted a conditional no-action position permitting certain special purpose broker-dealers to custody digital asset securities under Rule 15c3–3 under the Exchange Act (the ''Custody Statement''); [26] in September 2020, the Staff of the Commission released a no-action letter permitting certain broker-dealers to operate a non-custodial Alternative Trading System (''ATS'') for digital asset securities, subject to specified conditions; [27] in October 2019, the Staff of the Commission granted temporary relief from the clearing agency registration requirement to an entity seeking to establish a securities clearance and settlement system based on distributed ledger technology,[28] and multiple transfer agents who provide services for digital asset securities registered with the Commission.[29]

Outside the Commission's purview, the regulatory landscape has changed significantly since 2016, and cryptocurrency markets have grown and evolved as well. The market for bitcoin is approximately 100 times larger, with a market cap of over $1 trillion.[30] According to the CME Bitcoin Futures Report, from October 25, 2021 through November 19, 2021, CFTC regulated bitcoin futures represented approximately $2.9 billion in notional trading volume on Chicago Mercantile Exchange (''CME'') (''CME Bitcoin Futures'') on a daily basis and notional volume was never below $1.2 billion per day.[31] Open interest was over $4 billion for the entirety of the period and at one point reached $5.5 billion. The CFTC has exercised its regulatory jurisdiction in bringing a number of enforcement actions related to bitcoin and against trading platforms that offer cryptocurrency trading.[32] The U.S. Office of the Comptroller of the Currency (the ''OCC'') has made clear that federally-chartered banks are able to provide custody services for cryptocurrencies and other digital assets.[33] The OCC recently granted conditional approval of two charter conversions by state-chartered trust companies to national banks, both of which provide cryptocurrency custody services.[34] NYDFS has granted no fewer than twenty-five BitLicenses, including to established public payment companies like PayPal Holdings, Inc. and Square, Inc., and limited purpose trust charters to entities providing cryptocurrency custody services, including the Trust's Custodian. The U.S. Treasury Financial Crimes Enforcement Network (''FinCEN'') has released extensive guidance regarding the applicability of the Bank Secrecy Act (''BSA'') and implementing regulations to virtual currency businesses,[35] and has proposed rules imposing requirements on entities subject to the BSA that are specific to the technological context of virtual currencies.[36] In addition, the Treasury's

'commodity' to include, among other things, 'all services, rights, and interests in which contracts for future delivery are presently or in the future dealt in.' 7 U.S.C. 1a(9). The definition of a 'commodity' is broad. *See, e.g., Board of Trade of City of Chicago* v. *SEC*, 677 F. 2d 1137, 1142 (7th Cir. 1982). Bitcoin and other virtual currencies are encompassed in the definition and properly defined as commodities.''

[21] A list of virtual currency businesses that are entities regulated by the NYDFS is available on the NYDFS website. *See https://www.dfs.ny.gov/apps_and_licensing/virtual_currency_businesses/regulated_entities.*

[22] Data as of March 31, 2016 according to publicly available filings. *See* Bitcoin Investment Trust Form S–1, dated May 27, 2016, available: *https://www.sec.gov/Archives/edgar/data/1588489/000095012316017801/filename1.htm.*

[23] *See* letter from Dalia Blass, Director, Division of Investment Management, U.S. Securities and Exchange Commission to Paul Schott Stevens, President & CEO, Investment Company Institute and Timothy W. Cameron, Asset Management Group—Head, Securities Industry and Financial Markets Association (January 18, 2018), *available at https://www.sec.gov/divisions/investment/noaction/2018/cryptocurrency-011818.htm.*

[24] *See* Prospectus supplement filed pursuant to Rule 424(b)(1) for INX Tokens (Registration No. 333–233363), *available at: https://www.sec.gov/Archives/edgar/data/1725882/000121390020023202/ea125858-424b1_inxlimited.htm.*

[25] *See* Prospectus filed by Stone Ridge Trust VI on behalf of NYDIG Bitcoin Strategy Fund Registration, *available at: https://www.sec.gov/Archives/edgar/data/1764894/000119312519309942/d693146d497.htm.*

[26] *See* Securities Exchange Act Release No. 90788, 86 FR 11627 (February 26, 2021) (File Number S7–25–20) (Custody of Digital Asset Securities by Special Purpose Broker-Dealers).

[27] *See* letter from Elizabeth Baird, Deputy Director, Division of Trading and Markets, U.S. Securities and Exchange Commission to Kris Dailey, Vice President, Risk Oversight & Operational Regulation, Financial Industry Regulatory Authority (September 25, 2020), *available at: https://www.sec.gov/divisions/marketreg/mr-noaction/2020/finra-ats-role-in-settlement-of-digital-asset-security-trades-09252020.pdf.*

[28] *See* letter from Jeffrey S. Mooney, Associate Director, Division of Trading and Markets, U.S. Securities and Exchange Commission to Charles G. Cascarilla & Daniel M. Burstein, Paxos Trust Company, LLC (October 28, 2019), *available at: https://www.sec.gov/divisions/marketreg/mr-noaction/2019/paxos-trust-company-102819-17a.pdf.*

[29] *See, e.g.,* Form TA–1/A filed by Tokensoft Transfer Agent LLC (CIK: 0001794142) on January 8, 2021, *available at: https://www.sec.gov/Archives/edgar/data/1794142/000179414219000001/xslFTA1X01/primary_doc.xml.*

[30] As of December 1, 2021, the total market cap of all bitcoin in circulation was approximately $1.08 trillion.

[31] Data sourced from the CME Bitcoin Futures Report: 19 Nov, 2021, *available at: https://www.cmegroup.com/ftp/bitcoinfutures/Bitcoin_Futures_Liquidity_Report.pdf.*

[32] The CFTC's annual report for Fiscal Year 2020 (which ended on September 30, 2020) noted that the CFTC ''continued to aggressively prosecute misconduct involving digital assets that fit within the CEA's definition of commodity'' and ''brought a record setting seven cases involving digital assets.'' *See* CFTC FY2020 Division of Enforcement Annual Report, *available at: https://www.cftc.gov/media/5321/DOE_FY2020_AnnualReport_120120/download.* Additionally, the CFTC filed on October 1, 2020, a civil enforcement action against the owner/operators of the BitMEX trading platform, which was one of the largest bitcoin derivative exchanges. *See* CFTC Release No. 8270–20 (October 1, 2020) *available at: https://www.cftc.gov/PressRoom/PressReleases/8270-20.*

[33] *See* OCC News Release 2021–2 (January 4, 2021) *available at: https://www.occ.gov/news-issuances/news-releases/2021/nr-occ-2021-2.html.*

[34] *See* OCC News Release 2021–6 (January 13, 2021) *available at: https://www.occ.gov/news-issuances/news-releases/2021/nr-occ-2021-6.html* and OCC News Release 2021–19 (February 5, 2021) *available at: https://www.occ.gov/news-issuances/news-releases/2021/nr-occ-2021-19.html.*

[35] *See* FinCEN Guidance FIN–2019–G001 (May 9, 2019) (Application of FinCEN's Regulations to Certain Business Models Involving Convertible Virtual Currencies) *available at: https://www.fincen.gov/sites/default/files/2019-05/FinCEN%20Guidance%20CVC%20FINAL%20508.pdf.*

[36] *See* U.S. Department of the Treasury Press Release: ''The Financial Crimes Enforcement

Continued

Office of Foreign Assets Control (''OFAC'') has brought enforcement actions over apparent violations of the sanctions laws in connection with the provision of wallet management services for digital assets.[37]

In addition to the regulatory developments laid out above, more traditional financial market participants have embraced and continue to embrace cryptocurrency: Large insurance companies,[38] asset managers,[39] university endowments,[40] pension funds,[41] and even historically bitcoin skeptical fund managers [42] are allocating to bitcoin. The largest over-the-counter bitcoin fund previously filed a Form 10 registration statement, which the Staff of the Commission reviewed and which took effect automatically, and is now a reporting company.[43] Established companies like Tesla, Inc.,[44] MicroStrategy Incorporated,[45] and Square, Inc.,[46] among others, have recently announced substantial investments in bitcoin in amounts as large as 43,200 BTC [47], worth around $2.5 billion (Tesla) valued at a BTCUSD price of $60,000 and 121,043 BTC worth $7.2 billion (MicroStrategy). The foregoing examples demonstrate that bitcoin has gained mainstream usage and recognition.

Despite these developments, access for U.S. retail investors to gain exposure to bitcoin via a transparent and U.S. regulated, U.S. exchange-traded vehicle remains limited. Instead current options include: (i) Paying a potentially high premium (and high management fees) to buy over-the-counter bitcoin funds (''OTC Bitcoin Funds''), to the advantage of more sophisticated investors that are able to create shares at net asset value (''NAV'') directly with the issuing trust; [48] (ii) facing the technical risk, complexity and generally high fees associated with buying spot bitcoin; (iii) purchasing shares of operating companies that they believe will provide proxy exposure to bitcoin with limited disclosure about the associated risks; [49] or (iv) through the purchase of Bitcoin Futures ETFs, which represent a sub-optimal structure for long-term investors that will cost them collectively tens of millions of dollars every year, as further discussed below. Meanwhile, investors in many other countries, including Canada [50] and Brazil, are able to use more traditional exchange listed and traded products (including exchange-traded funds

Network Proposes Rule Aimed at Closing Anti-Money Laundering Regulatory Gaps for Certain Convertible Virtual Currency and Digital Asset Transactions'' (December 18, 2020), *available at: https://home.treasury.gov/news/press-releases/sm1216.*

[37] *See* U.S. Department of the Treasury Enforcement Release: ''OFAC Enters Into $98,830 Settlement with BitGo, Inc. for Apparent Violations of Multiple Sanctions Programs Related to Digital Currency Transactions'' (December 30, 2020) *available at: https://home.treasury.gov/system/files/126/20201230_bitgo.pdf.*

[38] On December 10, 2020, Massachusetts Mutual Life Insurance Company (MassMutual) announced that it had purchased $100 million in bitcoin for its general investment account. *See* MassMutual Press Release ''Institutional Bitcoin provider NYDIG announces minority stake purchase by MassMutual'' (December 10, 2020) *available at: https://www.massmutual.com/about-us/news-and-press-releases/press-releases/2020/12/institutional-bitcoin-provider-nydig-announces-minority-stake-purchase-by-massmutual.*

[39] *See e.g.,* ''BlackRock's Rick Rieder says the world's largest asset manager has 'started to dabble' in bitcoin'' (February 17, 2021) *available at: https://www.cnbc.com/2021/02/17/blackrock-has-started-to-dabble-in-bitcoin-says-rick-rieder.html* and ''Guggenheim's Scott Minerd Says Bitcoin Should Be Worth $400,000'' (December 16, 2020) *available at: https://www.bloomberg.com/news/articles/2020-12-16/guggenheim-s-scott-minerd-says-bitcoin-should-be-worth-400-000.*

[40] *See e.g.,* ''Harvard and Yale Endowments Among Those Reportedly Buying Crypto'' (January 25, 2021) *available at: https://www.bloomberg.com/news/articles/2021-01-26/harvard-and-yale-endowments-among-those-reportedly-buying-crypto.*

[41] *See e.g.,* ''Virginia Police Department Reveals Why its Pension Fund is Betting on Bitcoin'' (February 14, 2019) *available at: https://finance.yahoo.com/news/virginia-police-department-reveals-why-194558505.html.*

[42] *See e.g.,* ''Bridgewater: Our Thoughts on Bitcoin'' (January 28, 2021) *available at: https://www.bridgewater.com/research-and-insights/our-thoughts-on-bitcoin* and ''Paul Tudor Jones says he likes bitcoin even more now, rally still in the 'first inning''' (October 22, 2020) *available at: https://www.cnbc.com/2020/10/22/-paul-tudor-jones-says-he-likes-bitcoin-even-more-now-rally-still-in-the-first-inning.html.*

[43] *See* Letter from Division of Corporation Finance, Office of Real Estate & Construction to Barry E. Silbert, Chief Executive Officer, Grayscale Bitcoin Trust (January 31, 2020) *https://www.sec.gov/Archives/edgar/data/1588489/000000000020000953/filename1.pdf.*

[44] *See* Form 10–K submitted by Tesla, Inc. for the fiscal year ended December 31, 2020 at 23: *https://www.sec.gov/ix?doc=/Archives/edgar/data/1318605/000156459021004599/tsla-10k_20201231.htm.*

[45] *See* Form 10–Q submitted by MicroStrategy Incorporated for the quarterly period ended September 30, 2020 at 8: *https://www.sec.gov/ix?doc=/Archives/edgar/data/1050446/000156459020047995/mstr-10q_20200930.htm.*

[46] *See* Form 10–Q submitted by Square, Inc. for the quarterly period ended September 30, 2020 at 51: *https://www.sec.gov/ix?doc=/Archives/edgar/data/1512673/000151267320000012/sq-20200930.htm.*

[47] Amount obtained from *https://bitcointreasuries.net* as of December 3, 2021.

[48] The largest OTC Bitcoin Fund has grown its AUM from approximately $2.6 billion on February 26, 2020, the date on which the Commission issued the disapproval order for the United States Bitcoin and Treasury Investment Trust, to $37.1 billion on December 1, 2021, according to Grayscale's website. *See* Securities Exchange Act Release No. 88284 (February 26, 2020), 85 FR 12595 (March 3, 2020) (SR–NYSEArca–2019–39) (the ''Wilshire Phoenix Disapproval''). While the price of one bitcoin has increased approximately 690% in the intervening period, the total AUM has increased by approximately 1540%, indicating that the increase in AUM was created beyond just price appreciation in bitcoin. The premium and discount for OTC Bitcoin Funds is known to move rapidly. For example, over the period of 12/21/20 to 1/21/20, the premium for the largest OTC Bitcoin Fund went from 40.18% to 2.79%. While the price of bitcoin appreciated significantly during this period and NAV per share increased by 41.25%, the price per share increased by only 3.58%. This means that investors are buying shares of a fund that experiences significant volatility in its premium and discount outside of the fluctuations in price of the underlying asset. Even operating within the normal premium and discount range, it's possible for an investor to buy shares of an OTC Bitcoin Fund only to have those shares quickly lose 10% or more in dollar value excluding any movement of the price of bitcoin. That is to say—the price of bitcoin could have stayed exactly the same from market close on one day to market open the next, yet the value of the shares held by the investor decreased only because of the fluctuation of the premium. As more investment vehicles, including mutual funds and ETFs, seek to gain exposure to bitcoin, the easiest option for a buy and hold strategy for such vehicles is often an OTC Bitcoin Fund, meaning that even investors that do not directly buy OTC Bitcoin Funds can be disadvantaged by extreme premiums (or discounts) and premium volatility.

[49] Recently a number of operating companies engaged in unrelated businesses—such as Tesla (a car manufacturer) and MicroStrategy (an enterprise software company)—have announced investments as large as $5.3 billion in bitcoin. Without access to bitcoin exchange-traded products, retail investors seeking investment exposure to bitcoin may end up purchasing shares in these companies in order to gain the exposure to bitcoin that they seek. In fact, mainstream financial news networks have written a number of articles providing investors with guidance for obtaining bitcoin exposure through publicly traded companies (such as MicroStrategy, Tesla, and bitcoin mining companies, among others) instead of dealing with the complications associated with buying spot bitcoin in the absence of a bitcoin ETP. *See e.g.,* ''7 public companies with exposure to bitcoin'' (February 8, 2021) available at: *https://finance.yahoo.com/news/7-public-companies-with-exposure-to-bitcoin-154201525.html;* and ''Want to get in the crypto trade without holding bitcoin yourself? Here are some investing ideas'' (February 19, 2021) available at: *https://www.cnbc.com/2021/02/19/ways-to-invest-in-bitcoin-without-holding-the-cryptocurrency-yourself-.html.* Such operating companies, however, are imperfect bitcoin proxies and provide investors with partial bitcoin exposure paired with a host of additional risks associated with whichever operating company they decide to purchase. Additionally, the disclosures provided by such operating companies with respect to risks relating to their bitcoin holdings are generally substantially smaller than the registration statement of a bitcoin ETP, including the Registration Statement, typically amounting to a few sentences of narrative description and a handful of risk factors. In other words, investors seeking bitcoin exposure through publicly traded companies are gaining only partial exposure to bitcoin and are not fully benefitting from the risk disclosures and associated investor protections that come from the securities registration process.

[50] The Exchange notes that the Purpose Bitcoin ETF, a retail physical bitcoin ETP launched in Canada, reportedly reached $1.2 billion in assets under management as of October 15, 2021 (''AUM''), demonstrating the demand for a North American market listed bitcoin exchange-traded product (''ETP''). The Purpose Bitcoin ETF also offers a class of units that is U.S. dollar denominated, which could appeal to U.S. investors.

holding physical bitcoin) to gain exposure to bitcoin, disadvantaging U.S. investors and leaving them with more risky means of getting bitcoin exposure.[51] Additionally, investors in other countries, specifically Canada, generally pay lower fees than U.S. retail investors that invest in OTC Bitcoin Funds due to the fee pressure that results from increased competition among available bitcoin investment options. Without an approved and regulated spot bitcoin ETP in the U.S. as a viable alternative, U.S. investors could seek to purchase shares of non-U.S. bitcoin vehicles in order to get access to bitcoin exposure. Given the separate regulatory regime and the potential difficulties associated with any international litigation, such an arrangement would create more risk exposure for U.S. investors than they would otherwise have with a U.S. exchange listed ETP. Further to this point, the lack of a U.S.-listed spot bitcoin ETP is not preventing U.S. funds from gaining exposure to bitcoin—several U.S. exchange-traded funds are using Canadian bitcoin ETPs to gain exposure to spot bitcoin. In addition to the benefits to U.S. investors articulated throughout this proposal, approving this proposal (and others like it) would provide U.S. exchange-traded funds with a U.S.-listed and regulated product to provide such access rather than relying on either flawed products or products listed and primarily regulated in other countries.

Bitcoin Futures ETFs

The Exchange and Sponsor applaud the Commission for allowing the recent launch of the ETFs registered under the Investment Company Act of 1940, as amended (the ''1940 Act''), that provide exposure to bitcoin through CME Bitcoin Futures (''Bitcoin Futures ETFs''). Allowing such products to list and trade is a productive first step in providing transparent, exchange-listed tools for expressing a view on bitcoin for U.S. investors and traders. However, as has been reported by numerous outlets, the structure of such products provides negative outcomes for buy and hold investors as compared to an ETP that would hold actual bitcoin instead of derivatives contracts (''Spot Bitcoin ETPs'').[52] Specifically, the cost of rolling CME Bitcoin Futures contracts (which has reached as high as 17% annually [53] excluding a fund's management fees and borrowing costs, if any) will cause the Bitcoin Futures ETFs to lag the performance of bitcoin itself and, at over a billion dollars in assets under management, would cost U.S. investors hundreds of millions of dollars on an annual basis. Such rolling costs would not be required for Spot Bitcoin ETPs that hold bitcoin. Further, Bitcoin Futures ETFs have grown so rapidly that they face potentially running into CME position limits, which would force a Bitcoin Futures ETF to invest in non-futures assets for bitcoin exposure and cause potential investor confusion and lack of certainty about what such Bitcoin Futures ETFs are actually holding to try to get exposure to bitcoin, not to mention completely changing the risk profile associated with such an ETF. While Bitcoin Futures ETFs represent a useful trading tool, they are clearly a sub-optimal structure for U.S. investors that are looking for long-term exposure to bitcoin that will, based on the calculations above, unnecessarily cost U.S. investors millions of dollars every year and the Exchange believes that any proposal to list and trade a Spot Bitcoin ETP should be reviewed by the Commission with this important investor protection context in mind.

As discussed further below, the Commission's primary test in determining whether to approve or disapprove a series of Commodity-Based Trust Shares, a product type which includes Spot Bitcoin ETPs, is whether the listing exchange has in place a comprehensive surveillance sharing agreement with a regulated market of significant size in the underlying asset. Previous disapproval orders have made clear that a regulated market of significant size is generally a futures and/or options market rather than the spot commodity markets, which are often unregulated.[54] Leaving aside the analysis of that standard for now,[55] Cboe believes it would be inconsistent to allow the listing and trading of Bitcoin Futures ETFs that hold primarily CME Bitcoin Futures while simultaneously disapproving Spot Bitcoin ETPs on the basis that the CME Bitcoin Futures market is not a regulated market of significant size. If the CME Bitcoin Futures market were not, in the opinion of the Commission, a regulated market of significant size, permitting Bitcoin Futures ETFs that trade on such market would seem to be inconsistent with the requirement under the Act of being designed to ''prevent fraudulent and manipulative acts and practices'' as articulated in the Winklevoss Order and other disapproval orders.[56] One may argue that the 1940 Act provides certain investor protections that could mitigate some of these concerns, but the investor protection mechanisms under the 1940 Act relate primarily to the composition of a 1940 Act fund's board of directors, limitations on leverage and transactions with affiliates, among others. Those requirements—which primarily relate to a 1940 Act fund's internal structure and operations, rather than to the markets for the assets which the 1940 Act fund trades—would not confer additional protections to investors in relation to the underlying CME Bitcoin Futures market that would justify different regulatory outcomes for Bitcoin Futures ETFs and Spot Bitcoin ETPs.[57]

Further to this point, part of the analysis of the regulated market of significant size test is whether an underlying market is sufficiently large to support an ETP is whether trading in the ETP is likely to be the predominant influence on prices in the market of

[51] The Exchange notes that securities regulators in a number of other countries have either approved or otherwise allowed the listing and trading of bitcoin ETPs. Specifically, these funds include the Purpose Bitcoin ETF, Bitcoin ETF, VanEck Vectors Bitcoin ETN, WisdomTree Bitcoin ETP, Bitcoin Tracker One, BTCetc bitcoin ETP, Amun Bitcoin ETP, Amun Bitcoin Suisse ETP, 21Shares Short Bitcoin ETP, CoinShares Physical Bitcoin ETP.

[52] *See e.g.,* ''Bitcoin ETF's Success Could Come at Fundholders' Expense,'' Wall Street Journal (October 24, 2021), available at: *https://www.wsj.com/articles/bitcoin-etfs-success-could-come-at-fundholders-expense-11635080580;* ''Physical Bitcoin ETF Prospects Accelerate,'' ETF.com (October 25, 2021), available at: *https://www.etf.com/sections/blog/physical-bitcoin-etf-prospects-shine?nopaging=1&__cf_chl_jschl_tk__=pmd_JsK.fjXz9eAQW9zol0qpzhXDrrlpIVdoCloLXbLjl44-1635476946-0-gqNtZGzNApCjcnBszQql.*

[53] *Id.*

[54] *See* Winklevoss Order at 37593, specifically footnote 202, which includes the language from numerous approval orders for which the underlying futures markets formed the basis for approving series of ETPs that hold physical metals, including gold, silver, palladium, platinum, and precious metals more broadly; and 37600, specifically where the Commission provides that ''when the spot market is unregulated—the requirement of preventing fraudulent and manipulative acts may possibly be satisfied by showing that the ETP listing market has entered into a surveillance-sharing agreement with a regulated market of significant size in derivatives related to the underlying asset.'' As noted above, the Exchange believes that these citations are particularly helpful in making clear that the spot market for a spot commodity ETP need not be ''regulated'' in order for a spot commodity ETP to be approved by the Commission, and in fact that it's been the common historical practice of the Commission to rely on such derivatives markets as the regulated market of significant size because such spot commodities markets are largely unregulated.

[55] As further outlined below, both the Exchange and the Sponsor believe that the CME Bitcoin Futures market represents a regulated market of significant size and that this proposal and others like it should be approved on this basis.

[56] 15 U.S.C. 78f(b)(5). For additional detail, *see* Winklevoss Order at 37600.

[57] The largest OTC Bitcoin Funds holding spot Bitcoin today are not 1940 Act Funds.

significant size.[58] According to publicly available data, the largest Bitcoin Futures ETF represents 3,803 contracts [59] of the total 9,625 contracts of open interest in December CME Bitcoin Futures [60] as of 12/2/21 (roughly 40% of open interest). This seems to directly contradict the previously articulated standards by the Commission in the disapproval orders issued for Spot Bitcoin ETPs related to whether the trading in the ETP would be the predominant influence on prices in that market.[61] While it is difficult at this point to assess the direct impact on pricing of the CME Bitcoin Futures based on the launch of the Bitcoin Futures ETFs, such circumstances, especially related to the generally predictable trading behaviors of an ETF, seem to have the potential to represent a significant influence over pricing in the market. Allowing Spot Bitcoin ETPs to come to market will alleviate these concerns because such ETPs would be transacting in the spot bitcoin market on a more limited basis (acquiring spot bitcoin as needed and not rolling contracts on a monthly basis). As further discussed below, research indicates that the CME Bitcoin Futures market is a regulated market of significant size that generally leads price discovery across USD-based trading in bitcoin futures and spot markets globally.

To the extent the Commission may view differential treatment of Bitcoin Futures ETFs and Spot Bitcoin ETPs as warranted based on the Commission's concerns about the custody of physical Bitcoin that a Spot Bitcoin ETP would hold (compared to cash-settled futures contracts),[62] the Sponsor believes this concern is mitigated to a significant degree by the custodial arrangements that the Trust has contracted with Coinbase Trust Company, LLC (the ''Custodian'') to provide. In the Custody Statement, the Commission stated that the fourth step that a broker-dealer could take to shield traditional securities customers and others from the risks and consequences of digital asset security fraud, theft, or loss is to establish, maintain, and enforce reasonably designed written policies, procedures, and controls for safekeeping and demonstrating the broker-dealer has exclusive possession or control over digital asset securities that are consistent with industry best practices to protect against the theft, loss, and unauthorized and accidental use of the private keys necessary to access and transfer the digital asset securities the broker-dealer holds in custody. While bitcoin is not a security and the Custodian is not a broker-dealer, the Sponsor believes that similar considerations apply to the Custodian's holding of the Trust's bitcoin. After diligent investigation, the Sponsor believes that the Custodian's policies, procedures, and controls for safekeeping, exclusively possessing, and controlling the Trust's bitcoin holdings are consistent with industry best practices to protect against the theft, loss, and unauthorized and accidental use of the private keys. As a trust company chartered by the New York Department of Financial Services, the Sponsor notes that the Custodian is subject to extensive regulation and has among the longest track records in the industry of providing custodial services for digital asset private keys. The Custodian has represented to the Trust that it has never suffered a loss of bitcoin belonging to customers. Under the circumstances, therefore, to the extent the Commission believes that its concerns about the risks of spot bitcoin custody justifies differential treatment of a Bitcoin Futures ETF versus a Spot Bitcoin ETP, the Sponsor believes that the fact that the Custodian employs the same types of policies, procedures, and safeguards in handling spot bitcoin that the Commission has stated that broker-dealers should implement with respect to digital asset securities would appear to weaken the justification for treating a Bitcoin Futures ETF compared to a Spot Bitcoin ETP differently due to spot bitcoin custody concerns.

Based on the foregoing, the Exchange and Sponsor believe that any objective review of the proposals to list Spot Bitcoin ETPs compared to the already listed and traded Bitcoin Futures ETFs would lead to the conclusion that Spot Bitcoin ETPs should be available to U.S. investors and, as such, this proposal and other comparable proposals to list and trade Spot Bitcoin ETPs should be approved by the Commission. Stated simply, U.S. investors stand to lose hundreds of millions of dollars from holding Bitcoin Futures ETFs, losses which could be prevented by the Commission approving Spot Bitcoin ETPs. Additionally, any concerns related to preventing fraudulent and manipulative acts and practices related to Spot Bitcoin ETPs would apply equally to the spot markets underlying the futures contracts held by a Bitcoin Futures ETF. While the 1940 Act does offer certain investor protections, those protections do not relate to mitigating potential manipulation of the holdings of an ETF in a way that warrants distinction between Bitcoin Futures ETFs and Spot Bitcoin ETPs. To be clear, both the Exchange and Sponsor believe that the CME Bitcoin Futures market is a regulated market of significant size and that such manipulation concerns are mitigated, as described extensively below. After allowing the listing and trading of Bitcoin Futures ETFs that hold primarily CME Bitcoin Futures, however, the only consistent outcome would be approving Spot Bitcoin ETPs on the basis that the CME Bitcoin Futures market is a regulated market of significant size. Including in the analysis the significant and preventable losses to U.S. investors that comes with Bitcoin Futures ETFs, disapproving Spot Bitcoin ETPs seems even more arbitrary and capricious. Given the current landscape, approving this proposal (and others like it) and allowing Spot Bitcoin ETPs to be listed and traded alongside Bitcoin Futures ETFs would establish a consistent regulatory approach, provide U.S. investors with choice in product structures for bitcoin exposure, and offer flexibility in the means of gaining exposure to bitcoin through transparent, regulated, U.S. exchange-listed vehicles.

Bitcoin Futures

CME began offering trading in CME Bitcoin Futures in December 2017. Each contract represents five bitcoin and is based on the CME CF Bitcoin Reference Rate.[63] The contracts trade and settle like other cash-settled commodity futures contracts. Nearly every measurable metric related to CME Bitcoin Futures has trended consistently up since launch and/or accelerated upward in the past year, which is captured in the following charts.

[58] *See* Winklevoss Order at 37594.

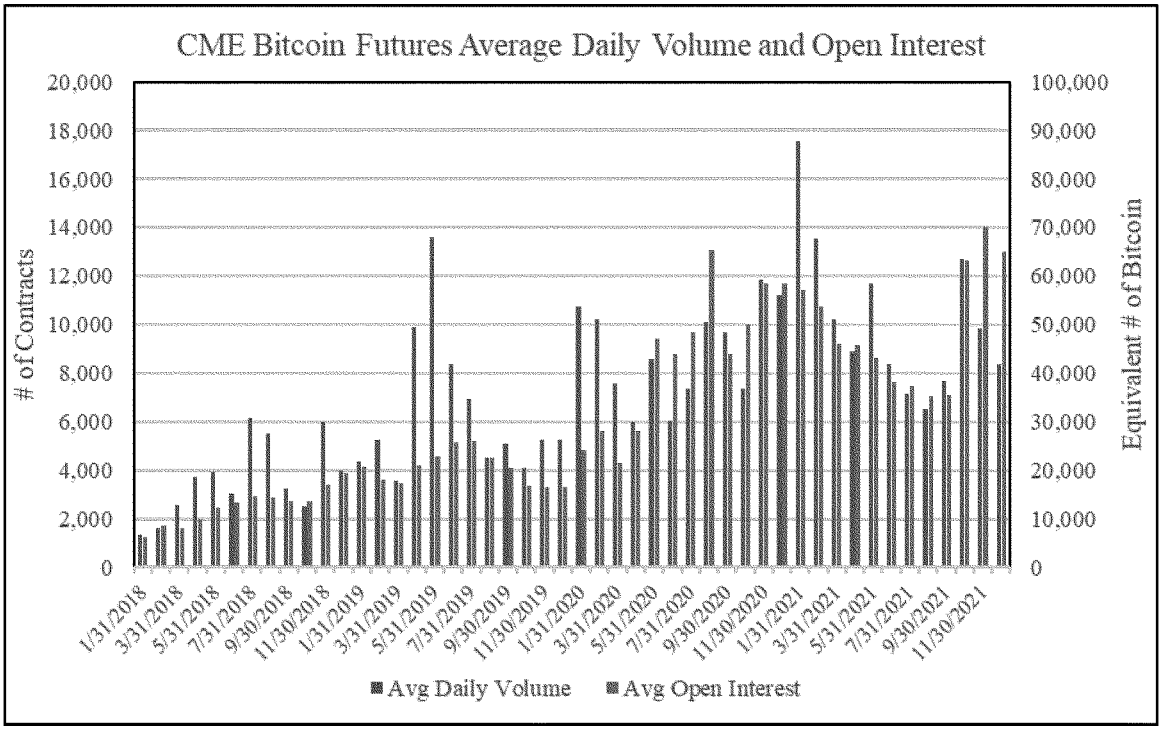
[59] *See* Fund Holdings Information available at *https://www.proshares.com/funds/bito.html.*

[60] *See* Volume and Open Interest data available at *https://www.cmegroup.com/markets/cryptocurrencies/bitcoin/bitcoin.volume.html.*

[61] *See* Winklevoss Order at 37594–37595.

[62] *See, e.g.,* Division of Investment Management Staff, Staff Statement on Funds Registered Under the Investment Company Act Investing in the Bitcoin Futures Market, May 11, 2021 (''The Bitcoin futures market also has not presented the custody challenges associated with some cryptocurrency-based investing because the futures are cash-settled'').

[63] According to CME, the CME CF Bitcoin Reference Rate aggregates the trade flow of major bitcoin spot exchanges during a specific calculation window into a once-a-day reference rate of the U.S. dollar price of bitcoin. Calculation rules are geared toward maximum transparency and real-time replicability in underlying spot markets, including Bitstamp, Coinbase, Gemini, itBit, and Kraken. For additional information, refer to *https://www.cmegroup.com/trading/cryptocurrency-indices/cf-bitcoin-reference-rate.html?redirect=/trading/cf-bitcoin-reference-rate.html.*



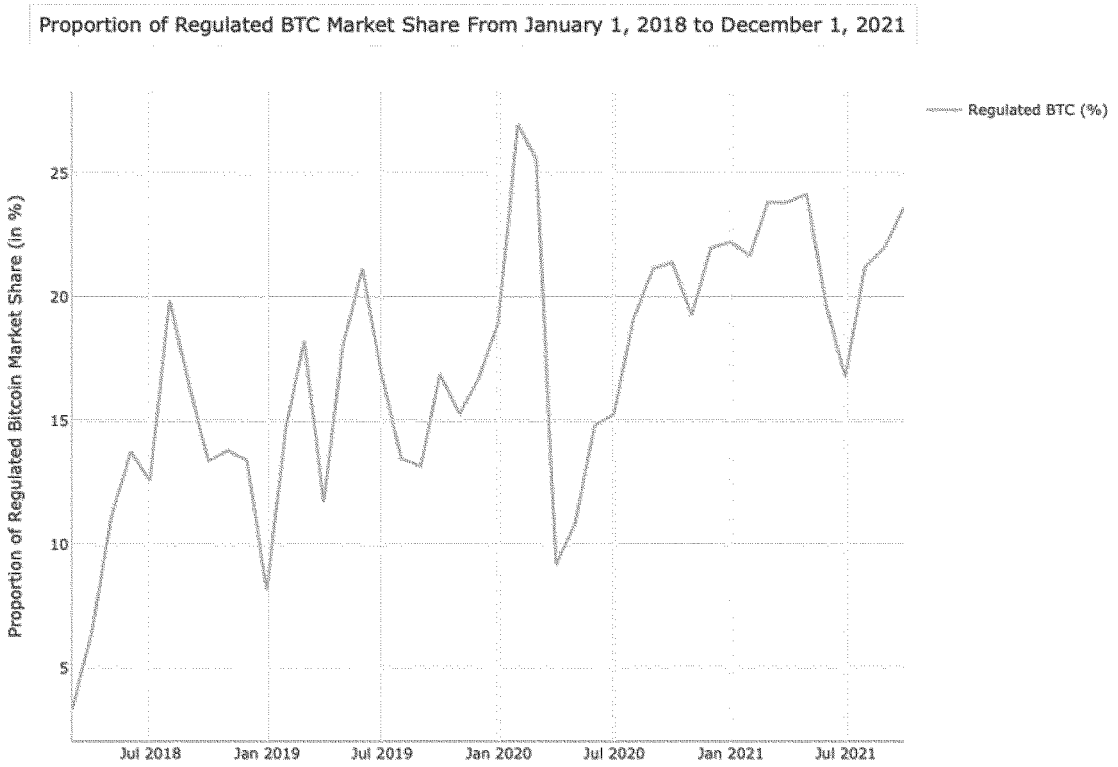
Additional Analysis [64]

According to the Sponsor, the increase in the volume on the CME is reflected in a higher proportion of the bitcoin market share. This is illustrated by plotting the proportion of monthly volume traded in bitcoin on the CME [65] (categorized as regulated in the chart and used as the numerator) in relation to the total bitcoin market, which comprises of the sum of the volume of bitcoin futures on the CME and the spot volume on cryptocurrency exchanges [66] (categorized as unregulated and used as the denominator) from January 1, 2018 to December 1, 2021 illustrates this point.

[64] Unless otherwise noted, all data and analysis presented in this section and referenced elsewhere in the filing has been provided by the Sponsor.

[65] Data on Bitcoin futures is obtained from *https://www.cmegroup.com/markets/cryptocurrencies/bitcoin/bitcoin.volume.html.*

[66] Data on Bitcoin volume traded on cryptocurrency exchanges is obtained from *https://www.cryptocompare.com.*



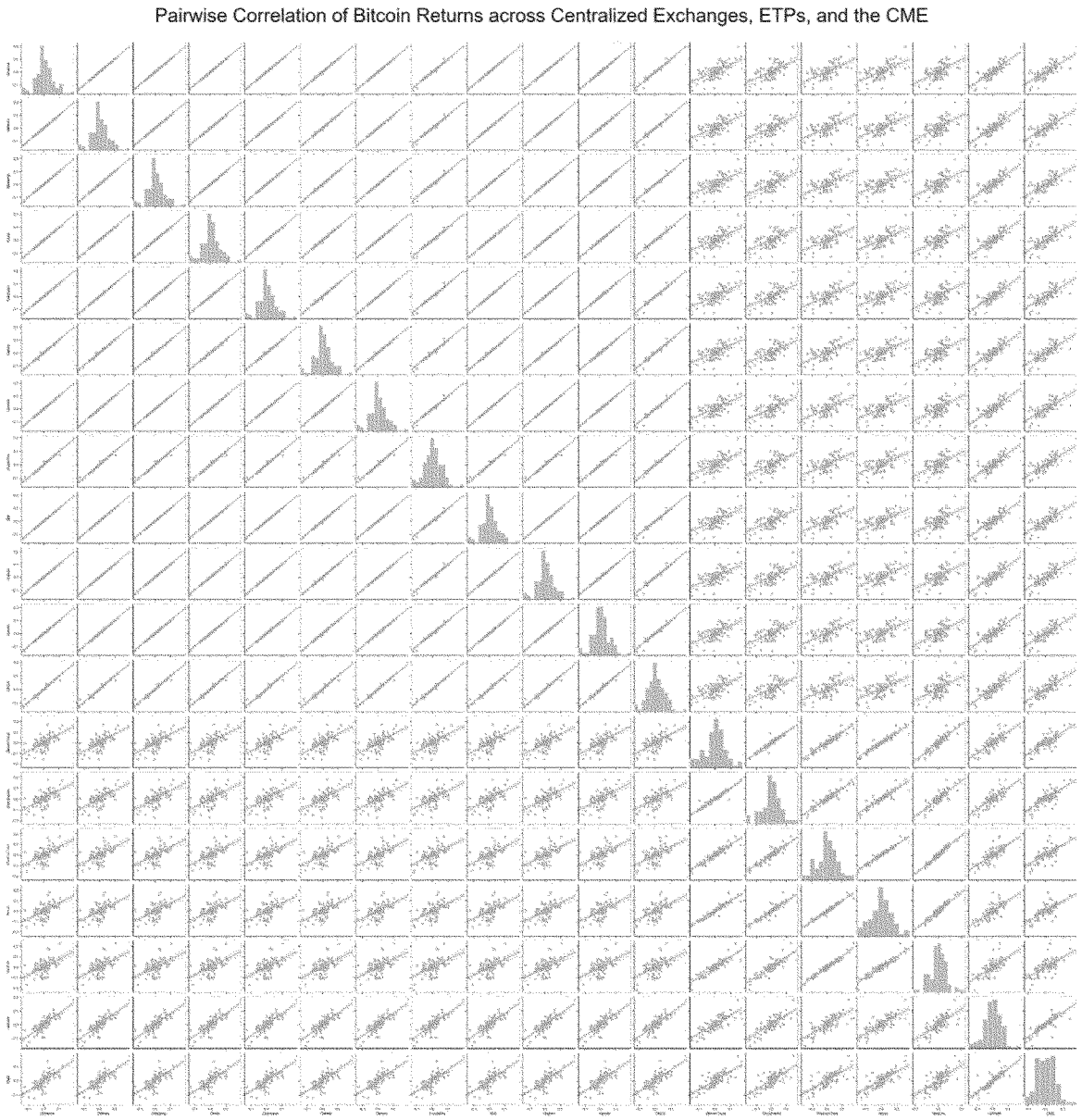
The proportion of volume traded on the CME has increased from less than 5% at inception, to more than 20% over three and a half years. Furthermore, the CME market, as well as other crypto-linked markets, and the spot market are highly correlated. In markets that are globally and efficiently integrated, one would expect that changes in prices of an asset across all markets to be highly correlated. The rationale behind this is that quick and efficient arbitrageurs would capture potentially profitable opportunities, consequently converging prices to the average intrinsic value very rapidly.

Bitcoin markets exhibit a high degree of correlation. Using daily Bitcoin prices from centralized exchanges, ETP providers, and the CME from January 20, 2021 to December 1, 2021,[67] the Sponsor calculates the Pearson correlation of returns[68] across these markets and find a high degree of correlation.

Correlations are between 57% and 99%, with the latter found mainly across centralized exchanges due to their higher level of interconnectedness. The lower correlations pertain mainly to the ETPs, which are relatively newer products and are mainly offered by a few competing market makers who are required to trade in large blocks, thus making it economically infeasible to capture small mispricings. As additional investors and arbitrageurs enter the market and capture the mispricing opportunities between these markets, it is likely that there will be much higher levels of correlations across all markets.

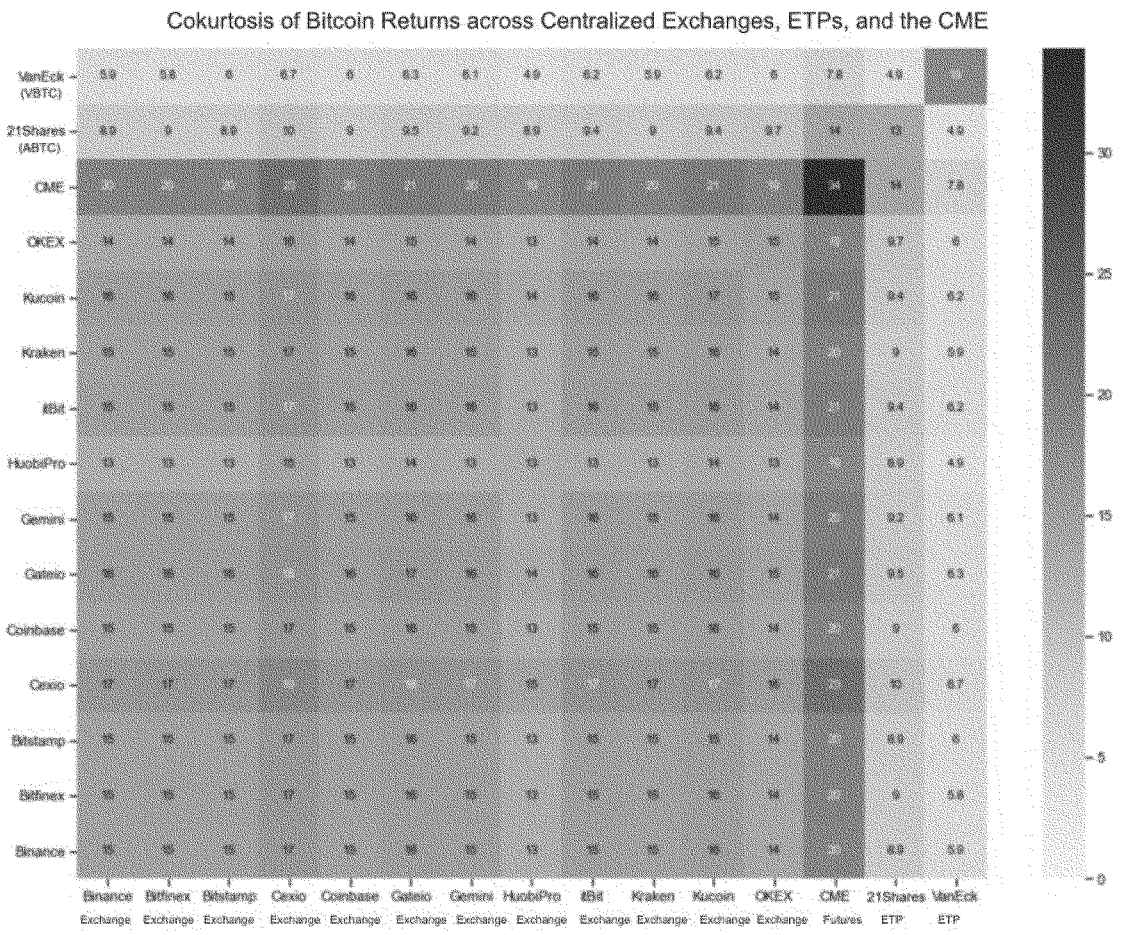
[67] The calculation of correlations used the period January 20, 2021 to December 1, 2021 as this is the common period across all the exchanges and data sources being analyzed.

[68] The Pearson correlation is a measure of linear association between two variables, and indicates the magnitude as well as direction of this relationship. The value can range between −1 (suggesting a strong negative association) and 1 (suggesting a strong positive association).



According to the Sponsor's research, this relationship holds true during periods of extreme price volatility. This implies that no single Bitcoin market can deviate significantly from the consensus for a prolonged period of time, such that the global Bitcoin market is sufficiently large and has an inherent unique resistance to manipulation. Hence, the Sponsor introduces a statistical component called cokurtosis, which measures to what extent two random variables change together. If two returns series exhibit a high degree of cokurtosis, this means that they tend to undergo extreme positive and negative changes simultaneously. A cokurtosis value larger than +3 or less than −3 is considered statistically significant. This table shows that the level of cokurtosis is positive and very high between all market combinations,[69] which suggests that Bitcoin markets tend to move very similarly especially for extreme price deviations. These results present evidence of a robust global Bitcoin market that quickly reacts in a unanimous manner to extreme price movements across both the spot markets, futures and ETP markets.

[69] The cokurtosis was calculated using hourly Bitcoin returns across centralized exchanges, ETPs—21Shares Bitcoin ETP (Ticker: ABTC) and VanEck Vectors Bitcoin ETN (Ticker: VBTC)—and CME Bitcoin Futures.



The Sponsor further believes that academic research corroborates the overall trend outlined above and supports the thesis that the CME Bitcoin Futures pricing leads the spot market and, thus, a person attempting to manipulate the Shares would also have to trade on that market to manipulate the ETP. Specifically, the Sponsor believes that such research supports the evidence in the literature (highlighted later on) that bitcoin futures lead the bitcoin spot market in price formation.[70]

Section 6(b)(5) and the Applicable Standards

The Commission has approved numerous series of Trust Issued Receipts,[71] including Commodity-Based Trust Shares,[72] to be listed on U.S. national securities exchanges. In order for any proposed rule change from an exchange to be approved, the Commission must determine that, among other things, the proposal is consistent with the requirements of Section 6(b)(5) of the Act, specifically including: (i) The requirement that a national securities exchange's rules are designed to prevent fraudulent and manipulative acts and practices; [73] and (ii) the requirement that an exchange proposal be designed, in general, to protect investors and the public interest. The Exchange believes that this proposal is consistent with the requirements of Section 6(b)(5) of the Act and that this filing sufficiently demonstrates that the CME Bitcoin Futures market represents a regulated market of significant size and that, on the whole, the manipulation concerns previously articulated by the

[70] *See* Hu, Y., Hou, Y. and Oxley, L. (2019). ''What role do futures markets play in Bitcoin pricing? Causality, cointegration and price discovery from a time-varying perspective'' (available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7481826/*). This academic research paper concludes that ''There exist no episodes where the Bitcoin spot markets dominates the price discovery processes with regard to Bitcoin futures. This points to a conclusion that the price formation originates solely in the Bitcoin futures market. We can, therefore, conclude that the Bitcoin futures markets dominate the dynamic price discovery process based upon time-varying information share measures. Overall, price discovery seems to occur in the Bitcoin futures markets rather than the underlying spot market based upon a time-varying perspective.''

[71] *See* Exchange Rule 14.11(f).

[72] Commodity-Based Trust Shares, as described in Exchange Rule 14.11(e)(4), are a type of Trust Issued Receipt.

[73] As the Exchange has stated in a number of other public documents, it continues to believe that bitcoin is resistant to price manipulation and that ''other means to prevent fraudulent and manipulative acts and practices'' exist to justify dispensing with the requisite surveillance sharing agreement. The geographically diverse and continuous nature of bitcoin trading render it difficult and prohibitively costly to manipulate the price of bitcoin. The fragmentation across bitcoin platforms, the relatively slow speed of transactions, and the capital necessary to maintain a significant presence on each trading platform make manipulation of bitcoin prices through continuous trading activity challenging. To the extent that there are bitcoin exchanges engaged in or allowing wash trading or other activity intended to manipulate the price of bitcoin on other markets, such pricing does not normally impact prices on other exchange because participants will generally ignore markets with quotes that they deem non-executable. Moreover, the linkage between the bitcoin markets and the presence of arbitrageurs in those markets means that the manipulation of the price of bitcoin price on any single venue would require manipulation of the global bitcoin price in order to be effective. Arbitrageurs must have funds distributed across multiple trading platforms in order to take advantage of temporary price dislocations, thereby making it unlikely that there will be strong concentration of funds on any particular bitcoin exchange or OTC platform. As a result, the potential for manipulation on a trading platform would require overcoming the liquidity supply of such arbitrageurs who are effectively eliminating any cross-market pricing differences.

Commission are sufficiently mitigated to the point that they are outweighed by quantifiable investor protection issues that would be resolved by approving this proposal.

(i) Designed To Prevent Fraudulent and Manipulative Acts and Practices

In order to meet this standard in a proposal to list and trade a series of Commodity-Based Trust Shares, the Commission requires that an exchange demonstrate that there is a comprehensive surveillance-sharing agreement in place [74] with a regulated market of significant size. Both the Exchange and CME are members of ISG.[75] The only remaining issue to be addressed is whether the CME Bitcoin Futures market constitutes a market of significant size, which both the Exchange and the Sponsor believe that it does. The terms ''significant market'' and ''market of significant size'' include a market (or group of markets) as to which: (a) There is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to manipulate the ETP, so that a surveillance-sharing agreement would assist the listing exchange in detecting and deterring misconduct; and (b) it is unlikely that trading in the ETP would be the predominant influence on prices in that market.[76]

The Commission has also recognized that the ''regulated market of significant size'' standard is not the only means for satisfying Section 6(b)(5) of the act, specifically providing that a listing exchange could demonstrate that ''other means to prevent fraudulent and manipulative acts and practices'' are sufficient to justify dispensing with the requisite surveillance-sharing agreement.[77]

(a) Manipulation of the ETP

The topic of price discovery in Bitcoin markets, including both spot and futures, has attracted the attention of many researchers. Nevertheless, despite the use of similar measures of price discovery, the literature has presented mixed evidence according to analysis by the Sponsor.

On the one hand, an early study by Corbet et al. (2018) [78] applied four metrics of price discovery including the information share approach of Hasbrouck (1995),[79] the component share methodology of Gonzalo and Granger (1995),[80] the information leadership approach of Yan and Zivot (2010),[81] and the information leadership share measure of Putnins (2013) [82] between the CME, CBOE, and spot prices using data sampled on a one-minute frequency. The authors find that price discovery is focused on the spot market. Similar evidence is presented by Baur and Dimpfl (2019),[83] where the authors use data sampled on a five-minute interval and conclude that price discovery occurs in the spot market.

On the other hand, a study by Kapar and Olmo (2019) [84] finds contradictory evidence using daily-sampled data, concluding that the CME futures market dominates price discovery based on the approaches of Gonzalo and Granger (1995) and Hasbrouck (1995). Similarly, Akyildirim et al. (2019) [85] show that Bitcoin futures play a significant role in price discovery relative to the spot market using the four previously mentioned measures of price discovery.

One potential reason for the mixed evidence, according to Hu et al. (2020) [86] is that cointegration relationships may go undetected if the underlying model formulation is constrained to be time-invariant. As such, the authors apply time-varying cointegrating coefficients based on the works of Park and Hahn (1999) [87] and Shi et al. (2018),[88] and conclude that futures prices Granger-cause spot prices and that futures prices dominate Bitcoin price discovery.

[74] As previously articulated by the Commission, ''The standard requires such surveillance-sharing agreements since ''they provide a necessary deterrent to manipulation because they facilitate the availability of information needed to fully investigate a manipulation if it were to occur.'' The Commission has emphasized that it is essential for an exchange listing a derivative securities product to enter into a surveillance- sharing agreement with markets trading underlying securities for the listing exchange to have the ability to obtain information necessary to detect, investigate, and deter fraud and market manipulation, as well as violations of exchange rules and applicable federal securities laws and rules. The hallmarks of a surveillance-sharing agreement are that the agreement provides for the sharing of information about market trading activity, clearing activity, and customer identity; that the parties to the agreement have reasonable ability to obtain access to and produce requested information; and that no existing rules, laws, or practices would impede one party to the agreement from obtaining this information from, or producing it to, the other party.'' The Commission has historically held that joint membership in the Intermarket Surveillance Group (''ISG'') constitutes such a surveillance sharing agreement. *See* Wilshire Phoenix Disapproval.

[75] For a list of the current members and affiliate members of ISG, *see www.isgportal.com.*

[76] *See* Wilshire Phoenix Disapproval.

[77] *See* Winklevoss Order at 37580. The Commission has also specifically noted that it ''is not applying a 'cannot be manipulated' standard; instead, the Commission is examining whether the proposal meets the requirements of the Exchange Act and, pursuant to its Rules of Practice, places the burden on the listing exchange to demonstrate the validity of its contentions and to establish that the requirements of the Exchange Act have been met.'' Id. at 37582.

[78] Corbet S., Lucey B., Peat M., Vigne S. Bitcoin futures—What use are they? Economics Letters. 2018;172:23–27.

[79] Hasbrouck J. One security, many markets: Determining the contributions to price discovery. The Journal of Finance. 1995;50(4):1175–1199.

[80] Gonzalo J., Granger C. Estimation of common long-memory components in cointegrated systems. Journal of Business & Economic Statistics. 1995;13(1):27–35.

[81] Yan B., Zivot E. A structural analysis of price discovery measures. Journal of Financial Markets. 2010;13(1):1–19.

[82] Putniņš T.J. What do price discovery metrics really measure? Journal of Empirical Finance. 2013;23:68–83.

[83] Baur D.G., Dimpfl T. Price discovery in bitcoin spot or futures? Journal of Futures Markets. 2019;39(7):803–817.

[84] Kapar B., Olmo J. An analysis of price discovery between Bitcoin futures and spot markets. Economics Letters. 2019;174:62–64.

[85] Akyildirim E., Corbet S., Katsiampa P., Kellard N., Sensoy A. The development of bitcoin futures: Exploring the interactions between cryptocurrency derivatives. Finance Research Letters. 2019;34:1–9.

[86] Hu, Yang et al. ''What role do futures markets play in Bitcoin pricing? Causality, cointegration and price discovery from a time-varying perspective?.'' International Review of Financial Analysis vol. 72 (2020): 101569.

[87] Park J.Y., Hahn S.B. Cointegrating regressions with time varying coefficients. Econometric Theory. 1999;15(5):664–703.

[88] Shi S., Phillips P.C., Hurn S. Change detection and the causal impact of the yield curve. Journal of Time Series Analysis. 2018;39(6):966–987.

Additionally, the Bitcoin futures market is by orders of magnitude larger than the entire spot market of all cryptoassets in terms of traded volume. According to a study by the Blockchain Lab of Massachusetts Institute of Technology, ''the derivative market leads price discovery of bitcoin more frequently than the spot markets. The spot market is more likely to indicate the direction of the price movement while the derivatives market is more likely to lead the magnitude of the price movement'', says the report.[89]

The Bitcoin futures market has processed more than $1 trillion in futures volume per month since the start of the year. In November 2021, Bitcoin futures volume accounted for $1.58 trillion, while spot volume, in the same time frame, amounted to $1.4 trillion including both crypto-only and fiat currency volumes of all cryptoassets, not just Bitcoin. Namely, the Bitcoin futures market is 12% larger than the entire spot market in terms of volume just in the last month. Over the past three months, the average monthly spot volume was $1.3 trillion while the average Bitcoin futures volume was significantly greater (approximately 30%) than the spot at $1.71 trillion.[90]

In the past twelve months, the average monthly futures volume for Bitcoin was $1.89 trillion, while the monthly spot volume for all cryptoassets was $1.24 trillion.[91] In other words, since the start of the year, the Bitcoin futures market is 52% larger than the spot volume of all cryptoassets traded on exchanges. As of December 2, 2021, the ratio of Bitcoin spot vs futures volume currently stands at 0.17.[92] In other words, the Bitcoin spot market accounts for 17% of the bitcoin futures market in volume terms.

Where CME Bitcoin Futures lead the price in the spot market such that a potential manipulator of the bitcoin spot market (beyond just the constituents of the Index[93]) would have to participate in the CME Bitcoin Futures market, it follows that a potential manipulator of the Shares would similarly have to transact in the CME Bitcoin Futures market because the Index is based on spot prices.

Further, the Trust only allows for in-kind creation and redemption, which, as further described below, reduces the potential for manipulation of the Shares through manipulation of the Index or any of its individual constituents, again emphasizing that a potential manipulator of the Shares would have to manipulate the entirety of the bitcoin spot market, which is led by the CME Bitcoin Futures market. As such, the Exchange believes that part (a) of the significant market test outlined above is satisfied and that common membership in ISG between the Exchange and CME would assist the listing exchange in detecting and deterring misconduct in the Shares.

(a) Predominant Influence on Prices in Spot and Bitcoin Futures

The Exchange and Sponsor also believe that trading in the Shares would not be the predominant force on prices in the CME Bitcoin Futures market or spot market for a number of reasons, including the significant volume in the CME Bitcoin Futures market, the size of bitcoin's market cap, and the significant liquidity available in the spot market. Moreover, the fact that the Shares are created in-kind means that they are fully collateralized and should remain close to NAV given that investors and market makers would arbitrage any significant price deviations between the price of the Shares and prices in the spot market. In addition to the CME Bitcoin Futures market data points cited above, the spot market for bitcoin is also very liquid. According to data from CoinRoutes from February 2021, the cost to buy or sell $5 million worth of bitcoin averages roughly 10 basis points with a market impact of 30 basis points.[94] For a $10 million market order, the cost to buy or sell is roughly 20 basis points with a market impact of 50 basis points. Stated another way, a market participant could enter a market buy or sell order for $10 million of bitcoin and only move the market 0.5%. More strategic purchases or sales (such as using limit orders and executing through OTC bitcoin trade desks) would likely have less obvious impact on the market—which is consistent with MicroStrategy, Tesla, and Square being able to collectively purchase billions of dollars in bitcoin. As such, the combination of CME Bitcoin Futures leading price discovery, the overall size of the bitcoin market, and the ability for market participants, including authorized participants creating and redeeming in-kind with the Trust, to buy or sell large amounts of bitcoin without significant market impact will help prevent the Shares from becoming the predominant force on pricing in either the bitcoin spot or CME Bitcoin Futures markets, satisfying part (b) of the test outlined above.

(b) Other Means to Prevent Fraudulent and Manipulative Acts and Practices

As noted above, the Commission also permits a listing exchange to demonstrate that ''other means to prevent fraudulent and manipulative acts and practices'' are sufficient to justify dispensing with the requisite surveillance-sharing agreement. The Exchange and Sponsor believe that such conditions are present. According to the Sponsor, a significant portion of the considerations around Bitcoin pricing have historically stemmed from a lack of consistent pricing across markets. However, according to the Sponsor's research, cross-exchange spreads in Bitcoin have been declining consistently over the past several years. Based on the daily Bitcoin price series from several popular centralized exchanges[95] the Sponsor has calculated the largest cross-exchange percentage spread (labelled as %C-Spread) by deducting the highest or maximum price (P) at time t from the lowest or minimum, and dividing by the lowest across all exchanges (i). Formally, this is expressed as:

$$\%C - Spread_t = \frac{max(P_{i,t}) - min(P_{i,t})}{min(P_{i,t})}$$

[89] Eguren, Luisa, Fondufe, Bryan, Hogan, Caleb, and Matthews, Claire. ''Price Discovery in the Bitcoin Spot and Derivatives Markets'' Massachusetts Institute of Technology Blockchain Lab Program, May 15th, 2020.

[90] According to data from CryptoCompare and Coinglass.

[91] *Id.*

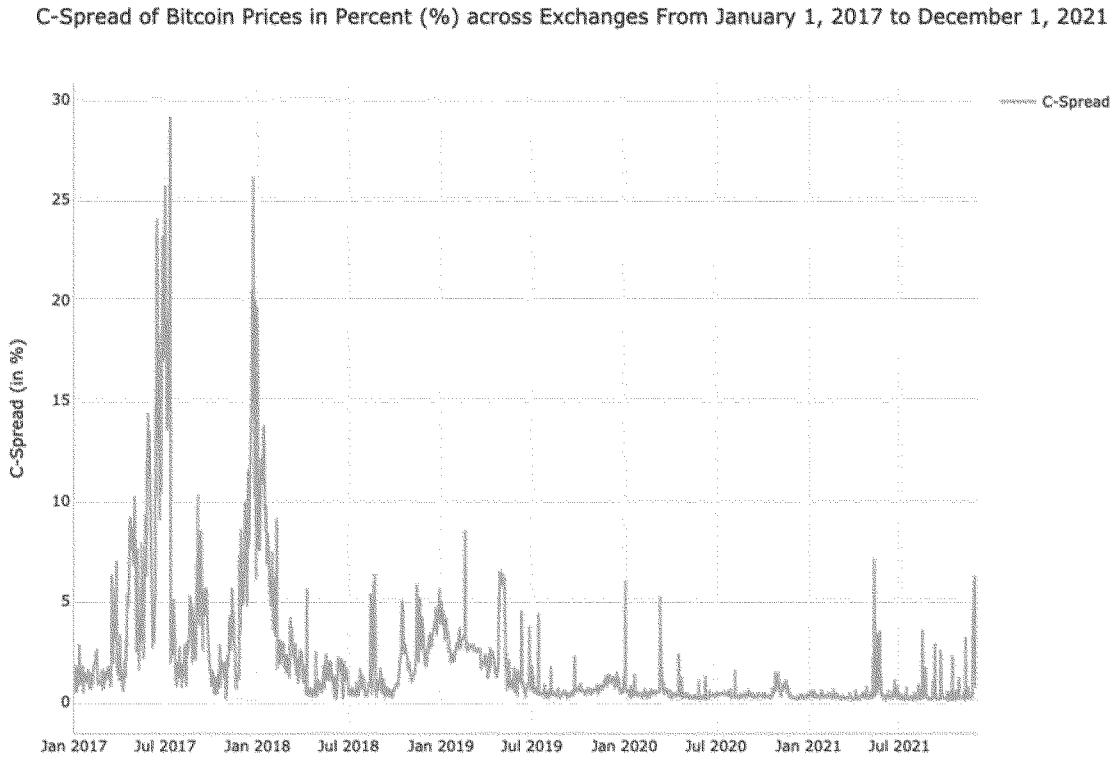
[92] *Id.*

[93] As further described below, the ''Index'' for the Fund is the S&P Bitcoin Index. The current exchange composition of the Index is Binance, Bitfinex, Bitflyer, Bittrex, Bitstamp, Coinbase Pro, Gemini, HitBTC, Huobi, Kraken, KuCoin, and Poloniex.

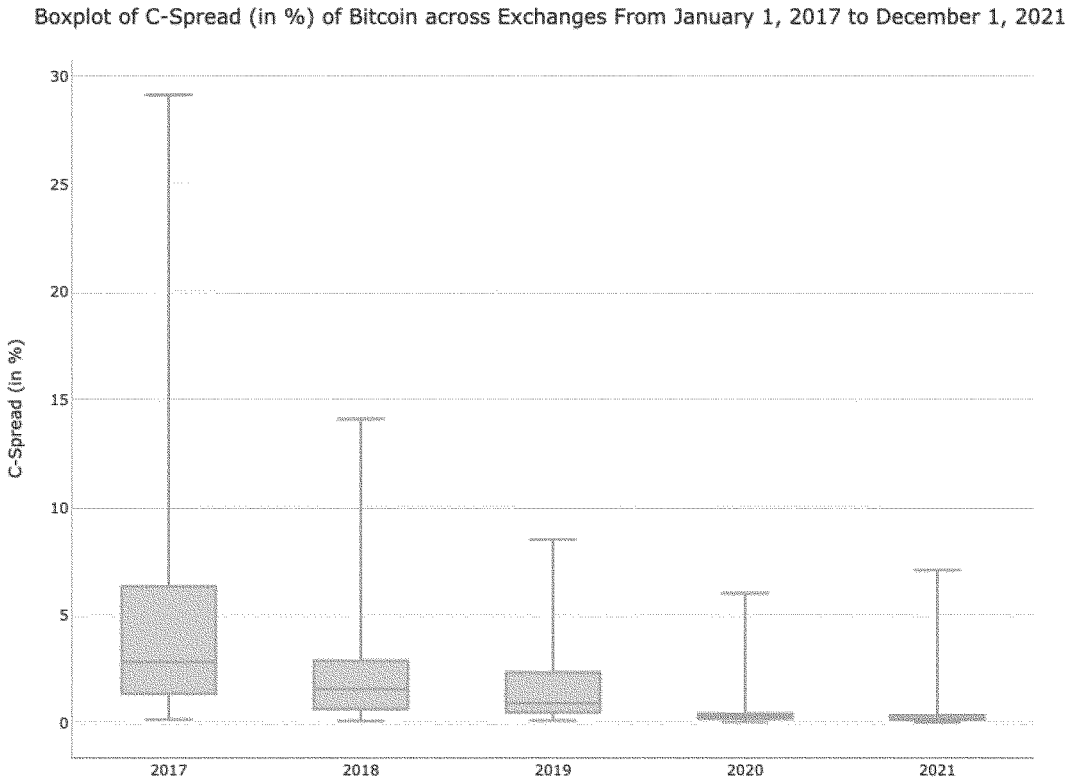
[94] These statistics are based on samples of bitcoin liquidity in USD (excluding stablecoins or Euro liquidity) based on executable quotes on Coinbase Pro, Gemini, Bitstamp, Kraken, LMAX Exchange, BinanceUS, and OKCoin during February 2021.

[95] The exchanges include Binance, Bitfinex, Bithumb, Bitstamp, Cexio, Coinbase, Coinone, Gateio, Gemini, HuobiPro, itBit, Kraken, Kucoin, and OKEX.

The results show a clear and sharp decline in the %C-Spread, indicating that the Bitcoin market has become more efficient as cross-exchange prices have converged over time.

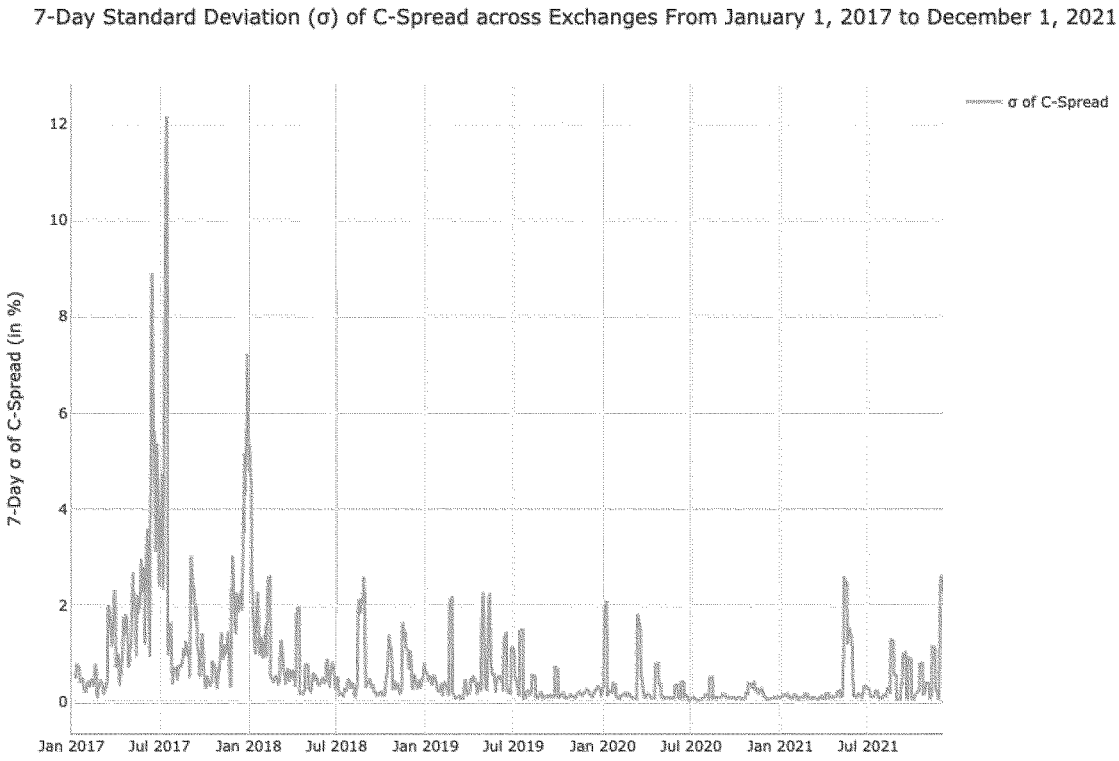


In addition, the magnitude of outlier % C-spreads has also declined over time. This boxplot shows that, not only did the median value of the %C-Spread decline over time, but also the extreme outlier values. For instance, the maximum %C-Spread for 2017, 2018, 2019, 2020, and 2021 are 29.14%, 14.45%, 8.54%, 6.04%, and 7.1%, respectively. The market has experienced a 38% year-on-year decline in the annual median %C-Spread indicating a greater degree of Bitcoin price convergence across exchanges and a more efficient market.

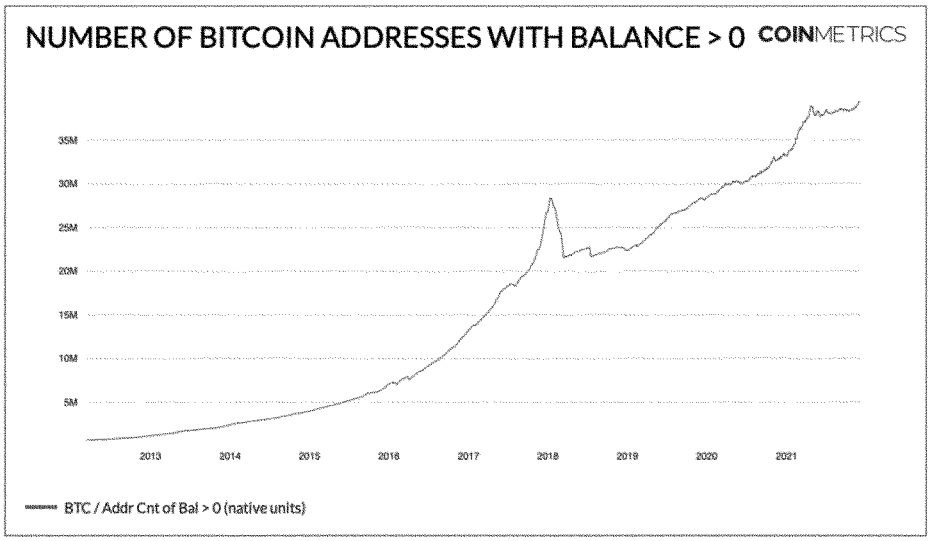


The dispersion (σ) of Bitcoin Prices has also declined over the same period. This chart shows the 7-day rolling standard deviation of the %C-Spread from January 1, 2017 to December 1, 2021. The Sponsor's research finds that the dispersion in Bitcoin prices across all exchanges has decreased over time, indicating that prices on all the considered exchanges converge towards the intrinsic average much more efficiently. This suggests that the market has become better at quickly reaching a consensus price for Bitcoin.

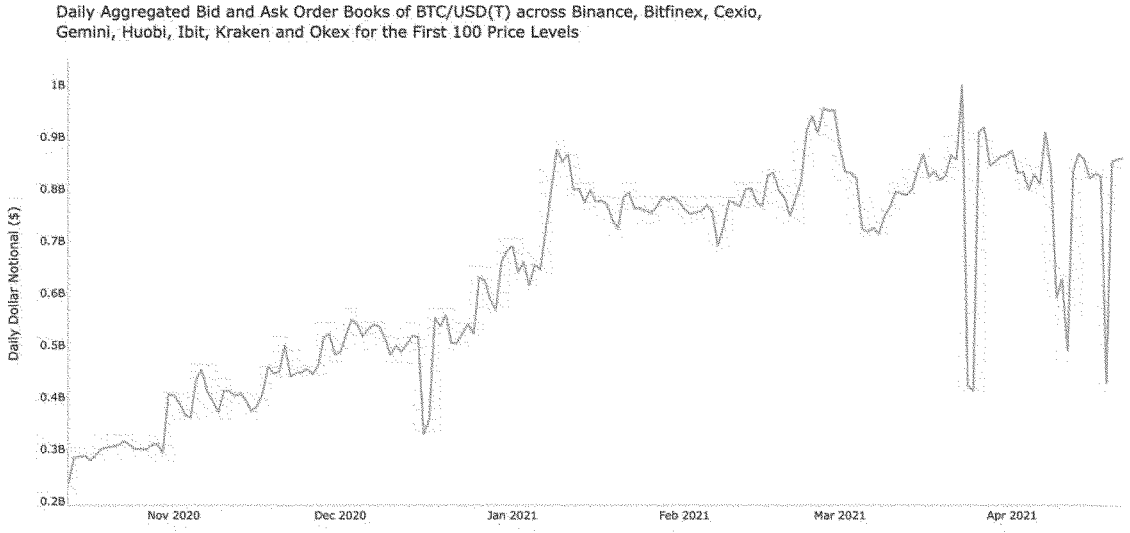
As the pricing of the Bitcoin market becomes increasingly efficient, pricing methodologies become more accurate and less susceptible to manipulation. The clustering of prices across a variety of sources within the primary market points towards robust price discovery mechanisms and efficient arbitrage.



One factor that has contributed to the overall efficiency, price discovery, and lower volatility of the Bitcoin market is the increase in the number of participants, and subsequently, the total dollar amount allocated to this market. This can be illustrated by the following chart, which shows the number of wallet addresses holding Bitcoin from March 2012 to December 2021.



The increase in the number of participants has manifested itself in higher liquidity in the market. This is exhibited in the following chart, which shows the daily aggregated dollar notional of the bid and ask order books within the first 100 price levels across several of the largest centralized crypto exchanges from October 2020 to April 2021. Specifically, the dollar notional that is allocated closest to the mid price has increased from around $230 million to $860 million over that period, representing a 270% increase in half a year.

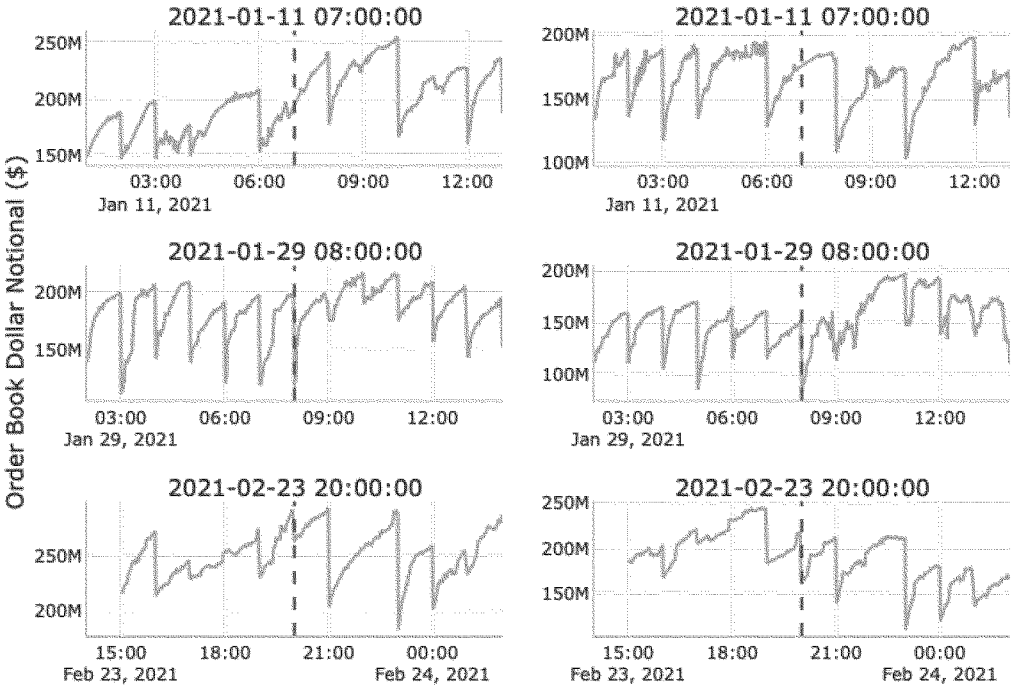


An increased notional order book suggests that there is a higher degree of consensus among investors regarding the price of Bitcoin. Moreover, this market characteristic hampers any attempt of price manipulation by any single large entity.

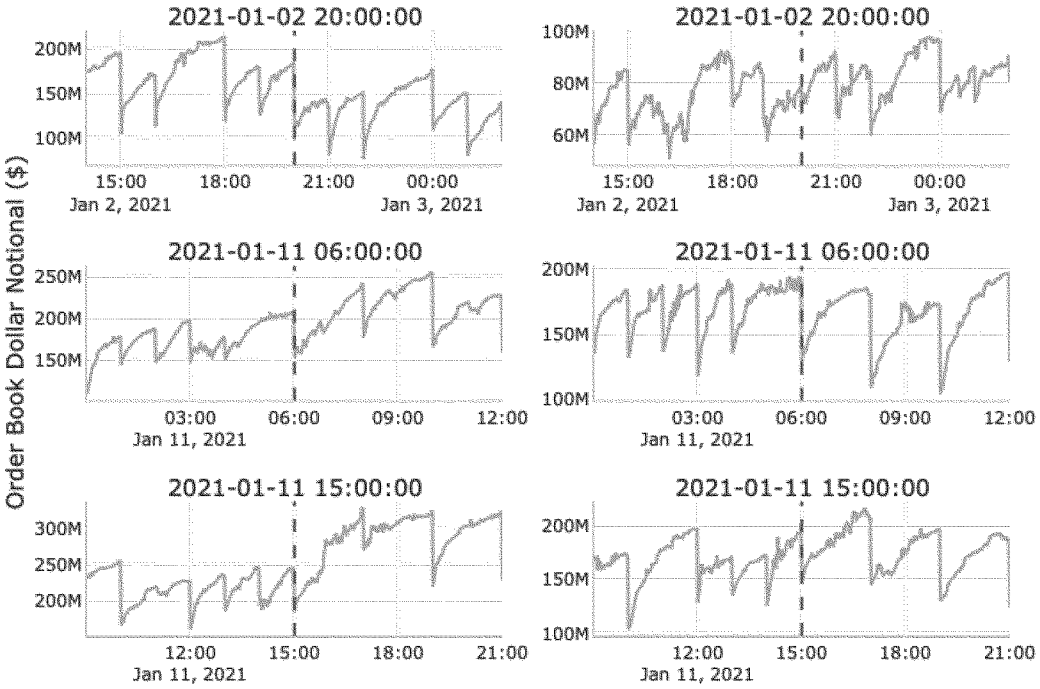
As a robustness check, the Sponsor investigates whether the dollar notional in the order book changes significantly prior to, and post an extreme price event. Specifically, for events constituting large increases in the price of Bitcoin, if the ask (or sell) side of the order book experiences a significant shrinkage in the dollar notional right before the event, then this may be an indication of market manipulation whereby the ask-side of the order book becomes sufficiently thin for a large order to move the price upward. Similarly, for events constituting large decreases in the price of Bitcoin, if the bid (or buy) side of the order book experiences a significant shrinkage in the dollar notional prior to such events, then this may be an indication of market manipulation whereby the thinner bid-side of the order book may potentially lead to significant downward price movements.

Using the top and bottom 0.1% of hourly price changes from October 2020 to April 2021 as events of extreme upward and downward market movements, respectively, the Sponsor plotted the bid (left charts) and ask (right charts) dollar notional of the Bitcoin order book within a six-hour window around these events in the chart below, which shows the results for extreme upward price movements. The extreme price events (indicated by the dashed green lines) perfectly coincide with the decrease in dollar notional of the ask-side of the order book. This is indicative of an efficient market, whereby large market movements are quickly and dynamically absorbed by a thick orderbook. Moreover, the dollar notional on the ask side after the event is replenished back to its pre-event level, which implies that market participants' reactions are quick to restore the market back to its equilibrium level.

Median Hourly Order Book Dollar Notional of Bid (Left Charts) and Ask (Right Charts) on Six Hours Pre and Post Extreme Price Deviations in the Top 0.1%



The same results and conclusions are found for extreme downward price movements. The charts below show that such price events perfectly coincide with shrinkages on the bid side of the order book (left charts), indicating an efficient and dynamic Bitcoin market. Moreover, the bid-side of the order book after the event is also restored back to its pre-event level, which suggests that the market is symmetrically efficient in moving back to equilibrium.



Finally, offering only in-kind creation and redemption will provide unique protections against potential attempts to manipulate the Shares. While the Sponsor believes that the Index which it uses to value the Trust's bitcoin is designed to reduce the risk of manipulation based on the methodology further described below, the fact that creations and redemptions are only available in-kind makes the manipulability of the Index significantly less important. Specifically, because the Trust will not accept cash to buy bitcoin in order to create new shares or, barring a forced redemption of the Trust or under other extraordinary circumstances, be forced to sell bitcoin to pay cash for redeemed shares, the price that the Sponsor uses to value the Trust's bitcoin is not particularly important.[96] When authorized participants are creating with the Trust, they need to deliver a certain number of bitcoin per share (regardless of the valuation used) and when they're redeeming, they can similarly expect to receive a certain number of bitcoin per share. As such, even if the price used to value the Trust's bitcoin is manipulated (which the Sponsor believes that its methodology is resistant to), the ratio of bitcoin per Share does not change and the Trust will either accept (for creations) or distribute (for redemptions) the same number of bitcoin regardless of the value. This not only mitigates the risk associated with potential manipulation, but also discourages and disincentivizes manipulation of the Index because there is little financial incentive to do so.

(ii) Designed To Protect Investors and the Public Interest

The Exchange believes that the proposal is designed to protect investors and the public interest. Over the past 1.5 years, U.S. investor exposure to bitcoin through OTC Bitcoin Funds has grown into the tens of billions of dollars and more than a billion dollars of exposure through Bitcoin Futures ETFs. With that growth, so too has grown the quantifiable investor protection issues to U.S. investors through roll costs for Bitcoin Futures ETFs and premium/discount volatility and management fees for OTC Bitcoin Funds. The Exchange believes that the concerns related to the prevention of fraudulent and manipulative acts and practices have been sufficiently addressed to be consistent with the Act. As such, the Exchange believes that approving this proposal (and comparable proposals) provides the Commission with the opportunity to allow U.S. investors with access to bitcoin in a regulated and transparent exchange-traded vehicle that would act to limit risk to U.S. investors by: (i) Reducing premium and discount volatility; (ii) reducing management fees through meaningful competition; (iii) reducing risks and costs associated with investing in Bitcoin Futures ETFs and operating companies that are imperfect proxies for bitcoin exposure; and (iv) providing an alternative for investors to self-custodying spot bitcoin.

ARK 21Shares Bitcoin ETF

Delaware Trust Company is the trustee (''Trustee''). The Bank of New York Mellon will be the administrator (''Administrator'') and transfer agent (''Transfer Agent''). Foreside Global Services, LLC will be the marketing agent (''Marketing Agent'') in connection with the creation and redemption of ''Baskets'' of Shares. ARK Investment Management LLC (''ARK'') will provide assistance in the marketing of the Shares. Coinbase Custody Trust Company, LLC, a third-party regulated custodian (the ''Custodian''), will be responsible for custody of the Trust's bitcoin.

According to the Registration Statement, each Share will represent a fractional undivided beneficial interest in the bitcoin held by the Trust. The Trust's assets will consist of bitcoin

[96] While the Index will not be particularly important for the creation and redemption process, it will be used for calculating fees.

held by the Custodian on behalf of the Trust. The Trust generally does not intend to hold cash or cash equivalents. However, there may be situations where the Trust will unexpectedly hold cash on a temporary basis.

According to the Registration Statement, the Trust is neither an investment company registered under the Investment Company Act of 1940, as amended,[97] nor a commodity pool for purposes of the Commodity Exchange Act (''CEA''), and neither the Trust nor the Sponsor is subject to regulation as a commodity pool operator or a commodity trading adviser in connection with the Shares.

When the Trust sells or redeems its Shares, it will do so in ''in-kind'' transactions in blocks of 5,000 Shares (a ''Creation Basket'') at the Trust's NAV. Authorized participants will deliver, or facilitate the delivery of, bitcoin to the Trust's account with the Custodian in exchange for Shares when they purchase Shares, and the Trust, through the Custodian, will deliver bitcoin to such authorized participants when they redeem Shares with the Trust. Authorized participants may then offer Shares to the public at prices that depend on various factors, including the supply and demand for Shares, the value of the Trust's assets, and market conditions at the time of a transaction. Shareholders who buy or sell Shares during the day from their broker may do so at a premium or discount relative to the NAV of the Shares of the Trust.

Investment Objective

According to the Registration Statement and as further described below, the investment objective of the Trust is to seek to track the performance of bitcoin, as measured by the performance of the S&P Bitcoin Index (the ''Index''), adjusted for the Trust's expenses and other liabilities. In seeking to achieve its investment objective, the Trust will hold bitcoin and will value the Shares daily based on the Index. The Trust will process all creations and redemptions in-kind in transactions with authorized participants. The Trust is not actively managed.

The Index

As described in the Registration Statement, the Fund will use the Index to calculate the Trust's NAV. The Index is a U.S. dollar-denominated composite reference rate for the price of bitcoin. There is no component other than bitcoin in the Index. The underlying exchanges are sourced by Lukka Inc. (the ''Data Provider'')[98] based on a combination of qualitative and quantitative metrics to analyze a comprehensive data set and evaluate factors including legal/regulation, KYC/transaction risk, data provision, security, team/exchange, asset quality/diversity, market quality and negative events. The Index price is currently sourced from the following set of exchanges: Binance, Bitfinex, Bitflyer, Bittrex, Bitstamp, Coinbase Pro, Gemini, HitBTC, Huobi, Kraken, KuCoin, and Poloniex. As the digital ecosystem continues to evolve, the Data Provider can add additional or remove exchanges based on the processes established by Lukka's Pricing Integrity Oversight Board.[99]

The Index methodology is intended to determine the fair market value (''FMV'') for bitcoin by determining the principal market for bitcoin as of 4 p.m. ET daily. The Index methodology uses a ranking approach that considers several exchange characteristics including oversight and intra-day trading volume. Specifically, to rank the credibility and quality of each exchange, the Data Provider dynamically assigns a Base Exchange Score (''BES'') score to the key characteristics for each exchange.

The BES reflects the fundamentals of an exchange and determines which exchange should be designated as the principal market at a given point of time. This score is determined by computing a weighted average of the values assigned to four different exchange characteristics. The exchange characteristics are as follows: (i) Oversight; (ii) microstructure efficiency; (iii) data transparency and (iv) data integrity.

Oversight

This score reflects the rules in place to protect and to give access to the investor. The score assigned for exchange oversight will depend on parameters such as jurisdiction, regulation, ''Know Your Customer and Anti-Money Laundering Compliance'' (KYC/AML), among other proprietary factors.

Microstructure Efficiency

The effective bid ask spread is used as a proxy for efficiency. For example, for each exchange and currency pair, the Data Provider takes an estimate of the ''effective spread'' relative to the price.

Data Transparency

Transparency is the term used for a quality score that is determined by the level of detail of the data offered by an exchange. The most transparent exchanges offer order-level data, followed by order book, trade-level, and then candles.

Data Integrity

Data integrity reconstructs orders to ensure the transaction amounts that make up an order equal the overall order amount matching on both a minute and daily basis. This data would help expose nefarious actions such as wash trading or other potential manipulation of data.

The methodology then applies a five-step weighting process for identifying a principal exchange and the last price on that exchange. Following this weighting process, an executed exchange price is assigned for bitcoin as of 4 p.m. ET. The Index price is determined according to the following procedure:

- *Step 1:* Assign each exchange a Base Exchange Score (''BES'') reflecting static exchange characteristics such as oversight, microstructure and technology, as discussed below.
- *Step 2:* Adjust the BES based on the relative monthly volume each exchange services. This new score is the Volume Adjusted Score (''VAS'').
- *Step 3:* Decay the VAS based on the time passed since the last trade on the exchange. Here, the Data Provider is assessing the level of activity in the market by considering the frequency (volume) of trades. The decay factor reflects the time since the last trade on the exchange. This is the final Decayed Volume Adjusted Score (''DVAS''), which tracks the freshness of the data by tracking most recent trades.
- *Step 4:* Rank the exchanges by the DVAS score and designate the highest-ranking exchange as the principal market for that point in time. The principal market is the exchange with the highest DVAS.
- *Step 5:* After selecting a primary exchange, an executed exchange price is used for bitcoin representing FMV at 4 p.m. ET. The Data Provider takes the last traded prices at that moment in time on that trading venue for the relevant

[97] 15 U.S.C. 80a–1.

[98] Lukka is an independent third-party digital asset data company engaged by the Sponsor to provide fair market value (FMV) bitcoin prices. This price, commercially available from Lukka, will form the basis for determining the value of the Trust's Bitcoin Holdings. Lukka is not affiliated with the Trust or the Sponsor other than through a commercial relationship. All of Lukka's products are also SOC 1 and 2 Type 2 certified.

[99] The purpose of Lukka's Pricing Integrity Oversight Board is to ensure (i) the integrity and validity of the Lukka pricing and valuation products and (ii) the Lukka pricing and valuation products remain fit for purpose in the rapidly evolving market and corresponding regulatory environments.

pair (Bitcoin/USD) when determining the Index price.

As discussed in the Registration Statement, the fact that there are multiple bitcoin spot markets that may contribute prices to the Index price makes manipulation more difficult in a well-arbitraged and fractured market, as a malicious actor would need to manipulate multiple spot markets simultaneously to impact the Index price, or dramatically skew the historical distribution of volume between the various exchanges.

The Data Provider has designed a series of automated algorithms designed to supplement the core Lukka Prime Methodology in enhancing the ability to detect potentially anomalous price activity which could be detrimental to the goal of obtaining a Fair Market Value price that is representative of the market at a point in time.[100]

In addition to the automated algorithms, the Data Provider has dedicated resources and has established committees to ensure all prices are representative of the market. Any price challenges will result in an independent analysis of the price. This includes assessing whether the price from the selected exchange is biased according to analyses designed to recognize patterns consistent with manipulative activity, such as a quick reversion to previous traded levels following a sharp price change or any significant deviations from the volume weighted average price on a particular exchange or pricing on any other exchange included in the Lukka Prime eligibility universe. Policies and procedures for any adjustments to prices or changes to core parameters (*e.g.,* exchange selection) are described in the Lukka Price Integrity Manual.[101]

Upon detection or external referral of suspect manipulative activities, the case is raised to the Price Integrity Oversight Board. These checks occur on an on-going, intraday basis and any investigations are typically resolved promptly, in clear cases within minutes and in more complex cases same business day. The evidence uncovered shall be turned over to the Data Provider's Price Integrity Oversight Board for final decision and action. The Price Integrity Oversight Board may choose to pick an alternative primary market and may exclude such market from future inclusion in the Index methodology or choose to stand by the original published price upon fully evaluating all available evidence. It may also initiate an investigation of prior prices from such markets and shall evaluate evidence presented on a case-by-case basis.

After the Lukka Prime price is generated, the S&P DJI (''The Index Provider'') performs independent quality checks as a second layer of validation to those employed by the Data Provider, including checks against assets with large price movements, assets with missing prices, assets with zero prices, assets with unchanged prices, assets that have ceased pricing and assets where the price does not match the Lukka Prime primary exchange. The Index Provider may submit a price challenge to Lukka if any of the checks listed above are found to be material. Lukka will perform an independent review of the price challenge to ensure the price is representative of the fair value of a particular cryptocurrency. If there is a change, the process will follow that described in the Recalculation Policy found on the The Index Provider Digital Assets Indices Policies & Practices and Index Mathematics Methodology.

In addition, The Index Provider currently provides the below additional quality assurance mechanisms with respect to crypto price validation. These checks are based on current market conditions, internal system processes and other assessments. The Index Provider reserves the right within its sole discretion to supplement, modify and/or remove individual checks and/or the parameters used within the checks, at any time without notice.

Crypto Price and Exchange Validation

- Check for any assets with no price received from Lukka;
- Check for any assets with a zero price received from Lukka;
- Check for any assets with a large change from the previous day. (Outliers +/− 40%);
- Check for any assets with a stale price, aggregating the number of days the price remains stale;
- Confirm the Lukka price matches the Lukka Prime primary exchange price;
- Confirm the Lukka price is consistent with other Lukka Prime exchange prices;
- Check the volume of the Lukka Prime exchanges and challenge the Lukka primary exchange if the exchange is not within the top percentile of the trading volume for that asset;
- Aggregation of Lukka Prime primary exchange changes.

Availability of Information

In addition to the price transparency of the Index, the Trust will provide information regarding the Trust's bitcoin holdings as well as additional data regarding the Trust. The Trust will provide an Intraday Indicative Value (''IIV'') per Share updated every 15 seconds, as calculated by the Exchange or a third-party financial data provider during the Exchange's Regular Trading Hours (9:30 a.m. to 4:00 p.m. E.T.). The IIV will be calculated by using the prior day's closing NAV per Share as a base and updating that value during Regular Trading Hours to reflect changes in the value of the Trust's bitcoin holdings during the trading day.

The IIV disseminated during Regular Trading Hours should not be viewed as an actual real-time update of the NAV, which will be calculated only once at the end of each trading day. The IIV will be widely disseminated on a per Share basis every 15 seconds during the Exchange's Regular Trading Hours by one or more major market data vendors. In addition, the IIV will be available through on-line information services.

The website for the Trust, which will be publicly accessible at no charge, will contain the following information: (a) The current NAV per Share daily and the prior business day's NAV and the reported closing price; (b) the BZX Official Closing Price [102] in relation to the NAV as of the time the NAV is calculated and a calculation of the premium or discount of such price against such NAV; (c) data in chart form displaying the frequency distribution of discounts and premiums of the Official Closing Price against the NAV, within appropriate ranges for each of the four previous calendar quarters (or for the life of the Trust, if shorter); (d) the prospectus; and (e) other applicable quantitative information. The Trust will also disseminate the Trust's holdings on a daily basis on the Trust's website. The price of bitcoin will be made available by one or more major market data vendors, updated at least every 15 seconds during Regular Trading Hours. Information about the Index, including key elements of how the Index is calculated, will be publicly available at *https://www.spglobal.com/spdji/en/indices/digital-assets/sp-bitcoin-index//*.

The NAV for the Trust will be calculated by the Administrator once a day and will be disseminated daily to all market participants at the same time. Quotation and last-sale information

[100] Upon request, Lukka can provide additional information and detail to the Commission regarding the algorithms and data quality checks that are put in place, with confidential treatment requested.

[101] Upon request, Lukka can provide the Commission the Lukka Pricing Integrity Manual, with confidential treatment requested.

[102] As defined in Rule 11.23(a)(3), the term ''BZX Official Closing Price'' shall mean the price disseminated to the consolidated tape as the market center closing trade.

regarding the Shares will be disseminated through the facilities of the Consolidated Tape Association (''CTA'').

Quotation and last sale information for bitcoin is widely disseminated through a variety of major market data vendors, including Bloomberg and Reuters, as well as the Index. Information relating to trading, including price and volume information, in bitcoin is available from major market data vendors and from the exchanges on which bitcoin are traded. Depth of book information is also available from bitcoin exchanges. The normal trading hours for bitcoin exchanges are 24 hours per day, 365 days per year.

Net Asset Value

NAV means the total assets of the Trust including, but not limited to, all bitcoin and cash less total liabilities of the Trust, each determined on the basis of generally accepted accounting principles. The Administrator determines the NAV of the Trust on each day that the Exchange is open for regular trading, as promptly as practical after 4:00 p.m. EST. The NAV of the Trust is the aggregate value of the Trust's assets less its estimated accrued but unpaid liabilities (which include accrued expenses). In determining the Trust's NAV, the Administrator values the bitcoin held by the Trust based on the price set by the Index as of 4:00 p.m. EST. The Administrator also determines the NAV per Share.

Creation and Redemption of Shares

According to the Registration Statement, on any business day, an authorized participant may place an order to create one or more baskets. Purchase orders must be placed by 4:00 p.m. Eastern Time, or the close of regular trading on the Exchange, whichever is earlier. The day on which an order is received is considered the purchase order date. The total deposit of bitcoin required is an amount of bitcoin that is in the same proportion to the total assets of the Trust, net of accrued expenses and other liabilities, on the date the order to purchase is properly received, as the number of Shares to be created under the purchase order is in proportion to the total number of Shares outstanding on the date the order is received. Each night, the Sponsor will publish the amount of bitcoin that will be required in exchange for each creation order. The Administrator determines the required deposit for a given day by dividing the number of bitcoin held by the Trust as of the opening of business on that business day, adjusted for the amount of bitcoin constituting estimated accrued but unpaid fees and expenses of the Trust as of the opening of business on that business day, by the quotient of the number of Shares outstanding at the opening of business divided by 5,000. The procedures by which an authorized participant can redeem one or more Creation Baskets mirror the procedures for the creation of Creation Baskets.

Rule 14.11(e)(4)—Commodity-Based Trust Shares

The Shares will be subject to BZX Rule 14.11(e)(4), which sets forth the initial and continued listing criteria applicable to Commodity-Based Trust Shares. The Exchange will obtain a representation that the Trust's NAV will be calculated daily and that these values and information about the assets of the Trust will be made available to all market participants at the same time. The Exchange notes that, as defined in Rule 14.11(e)(4)(C)(i), the Shares will be: (a) Issued by a trust that holds a specified commodity [103] deposited with the trust; (b) issued by such trust in a specified aggregate minimum number in return for a deposit of a quantity of the underlying commodity; and (c) when aggregated in the same specified minimum number, may be redeemed at a holder's request by such trust which will deliver to the redeeming holder the quantity of the underlying commodity.

Upon termination of the Trust, the Shares will be removed from listing. The Trustee, Delaware Trust Company, is a trust company having substantial capital and surplus and the experience and facilities for handling corporate trust business, as required under Rule 14.11(e)(4)(E)(iv)(a) and that no change will be made to the trustee without prior notice to and approval of the Exchange. The Exchange also notes that, pursuant to Rule 14.11(e)(4)(F), neither the Exchange nor any agent of the Exchange shall have any liability for damages, claims, losses or expenses caused by any errors, omissions or delays in calculating or disseminating any underlying commodity value, the current value of the underlying commodity required to be deposited to the Trust in connection with issuance of Commodity-Based Trust Shares; resulting from any negligent act or omission by the Exchange, or any agent of the Exchange, or any act, condition or cause beyond the reasonable control of the Exchange, its agent, including, but not limited to, an act of God; fire; flood; extraordinary weather conditions; war; insurrection; riot; strike; accident; action of government; communications or power failure; equipment or software malfunction; or any error, omission or delay in the reports of transactions in an underlying commodity. Finally, as required in Rule 14.11(e)(4)(G), the Exchange notes that any registered market maker (''Market Maker'') in the Shares must file with the Exchange in a manner prescribed by the Exchange and keep current a list identifying all accounts for trading in an underlying commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, which the registered Market Maker may have or over which it may exercise investment discretion. No registered Market Maker shall trade in an underlying commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, in an account in which a registered Market Maker, directly or indirectly, controls trading activities, or has a direct interest in the profits or losses thereof, which has not been reported to the Exchange as required by this Rule. In addition to the existing obligations under Exchange rules regarding the production of books and records (see, *e.g.,* Rule 4.2), the registered Market Maker in Commodity-Based Trust Shares shall make available to the Exchange such books, records or other information pertaining to transactions by such entity or registered or non-registered employee affiliated with such entity for its or their own accounts for trading the underlying physical commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, as may be requested by the Exchange.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares. The Exchange will halt trading in the Shares under the conditions specified in BZX Rule 11.18. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the bitcoin underlying the Shares; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to Rule

[103] For purposes of Rule 14.11(e)(4), the term commodity takes on the definition of the term as provided in the Commodity Exchange Act. As noted above, the CFTC has opined that Bitcoin is a commodity as defined in Section 1a(9) of the Commodity Exchange Act. *See* Coinflip.

14.11(e)(4)(E)(ii), which sets forth circumstances under which trading in the Shares may be halted.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. BZX will allow trading in the Shares during all trading sessions on the Exchange. The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in BZX Rule 11.11(a), the minimum price variation for quoting and entry of orders in securities traded on the Exchange is $0.01 where the price is greater than $1.00 per share or $0.0001 where the price is less than $1.00 per share.

Surveillance

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Commodity-Based Trust Shares. The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Trust or the Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Exchange Act, the Exchange will surveil for compliance with the continued listing requirements. If the Trust or the Shares are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12. The Exchange may obtain information regarding trading in the Shares and CME Bitcoin Futures via ISG, from other exchanges who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement.[104]

Information Circular

Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (i) The procedures for the creation and redemption of Baskets (and that the Shares are not individually redeemable); (ii) BZX Rule 3.7, which imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers; (iii) how information regarding the IIV and the Trust's NAV are disseminated; (iv) the risks involved in trading the Shares outside of Regular Trading Hours[105] when an updated IIV will not be calculated or publicly disseminated; (v) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (vi) trading information.

In addition, the Information Circular will advise members, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Shares. Members purchasing the Shares for resale to investors will deliver a prospectus to such investors. The Information Circular will also discuss any exemptive, no-action and interpretive relief granted by the Commission from any rules under the Act.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act[106] in general and Section 6(b)(5) of the Act[107] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Commission has approved numerous series of Trust Issued Receipts,[108] including Commodity-Based Trust Shares,[109] to be listed on U.S. national securities exchanges. In order for any proposed rule change from an exchange to be approved, the Commission must determine that, among other things, the proposal is consistent with the requirements of Section 6(b)(5) of the Act, specifically including: (i) The requirement that a national securities exchange's rules are designed to prevent fraudulent and manipulative acts and practices;[110] and (ii) the requirement that an exchange proposal be designed, in general, to protect investors and the public interest. The Exchange believes that this proposal is consistent with the requirements of Section 6(b)(5) of the Act and that this filing sufficiently demonstrates that the CME Bitcoin Futures market represents a regulated market of significant size and that, on the whole, the manipulation concerns previously articulated by the Commission are sufficiently mitigated to the point that they are outweighed by quantifiable investor protection issues that would be resolved by approving this proposal.

(i) Designed To Prevent Fraudulent and Manipulative Acts and Practices

In order to meet this standard in a proposal to list and trade a series of Commodity-Based Trust Shares, the Commission requires that an exchange demonstrate that there is a comprehensive surveillance-sharing agreement in place[111] with a regulated

[104] For a list of the current members and affiliate members of ISG, *see www.isgportal.com.*

[105] Regular Trading Hours is the time between 9:30 a.m. and 4:00 p.m. Eastern Time.

[106] 15 U.S.C. 78f.

[107] 15 U.S.C. 78f(b)(5).

[108] *See* Exchange Rule 14.11(f).

[109] Commodity-Based Trust Shares, as described in Exchange Rule 14.11(e)(4), are a type of Trust Issued Receipt.

[110] As the Exchange has stated in a number of other public documents, it continues to believe that ''other means to prevent fraudulent and manipulative acts and practices'' exist to justify dispensing with the requisite surveillance sharing agreement. The geographically diverse and continuous nature of bitcoin trading render it difficult and prohibitively costly to manipulate the price of bitcoin. The fragmentation across bitcoin platforms, the relatively slow speed of transactions, and the capital necessary to maintain a significant presence on each trading platform make manipulation of bitcoin prices through continuous trading activity challenging. To the extent that there are bitcoin exchanges engaged in or allowing wash trading or other activity intended to manipulate the price of bitcoin on other markets, such pricing does not normally impact prices on other exchange because participants will generally ignore markets with quotes that they deem non-executable. Moreover, the linkage between the bitcoin markets and the presence of arbitrageurs in those markets means that the manipulation of the price of bitcoin price on any single venue would require manipulation of the global bitcoin price in order to be effective. Arbitrageurs must have funds distributed across multiple trading platforms in order to take advantage of temporary price dislocations, thereby making it unlikely that there will be strong concentration of funds on any particular bitcoin exchange or OTC platform. As a result, the potential for manipulation on a trading platform would require overcoming the liquidity supply of such arbitrageurs who are effectively eliminating any cross-market pricing differences.

[111] As previously articulated by the Commission, ''The standard requires such surveillance-sharing agreements since ''they provide a necessary deterrent to manipulation because they facilitate the availability of information needed to fully investigate a manipulation if it were to occur.'' The Commission has emphasized that it is essential for an exchange listing a derivative securities product to enter into a surveillance-sharing agreement with markets trading underlying securities for the listing exchange to have the ability to obtain information necessary to detect, investigate, and deter fraud and market manipulation, as well as violations of exchange rules and applicable federal securities

market of significant size. Both the Exchange and CME are members of ISG.[112] The only remaining issue to be addressed is whether the CME Bitcoin Futures market constitutes a market of significant size, which both the Exchange and the Sponsor believe that it does. The terms ''significant market'' and ''market of significant size'' include a market (or group of markets) as to which: (a) There is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to manipulate the ETP, so that a surveillance-sharing agreement would assist the listing exchange in detecting and deterring misconduct; and (b) it is unlikely that trading in the ETP would be the predominant influence on prices in that market.[113]

The Commission has also recognized that the ''regulated market of significant size'' standard is not the only means for satisfying Section 6(b)(5) of the act, specifically providing that a listing exchange could demonstrate that ''other means to prevent fraudulent and manipulative acts and practices'' are sufficient to justify dispensing with the requisite surveillance-sharing agreement.[114]

laws and rules. The hallmarks of a surveillance-sharing agreement are that the agreement provides for the sharing of information about market trading activity, clearing activity, and customer identity; that the parties to the agreement have reasonable ability to obtain access to and produce requested information; and that no existing rules, laws, or practices would impede one party to the agreement from obtaining this information from, or producing it to, the other party.'' The Commission has historically held that joint membership in ISG constitutes such a surveillance sharing agreement. *See* Wilshire Phoenix Disapproval.

[112] For a list of the current members and affiliate members of ISG, *see www.isgportal.com.*

[113] *See* Wilshire Phoenix Disapproval.

[114] *See* Winklevoss Order at 37580. The Commission has also specifically noted that it ''is not applying a 'cannot be manipulated' standard; instead, the Commission is examining whether the proposal meets the requirements of the Exchange Act and, pursuant to its Rules of Practice, places the burden on the listing exchange to demonstrate the validity of its contentions and to establish that the requirements of the Exchange Act have been met.'' Id. at 37582.

(a) Manipulation of the ETP

The topic of price discovery in Bitcoin markets, including both spot and futures, has attracted the attention of many researchers. Nevertheless, despite the use of similar measures of price discovery, the literature has presented mixed evidence.

On the one hand, an early study by Corbet et al. (2018)[115] applied four metrics of price discovery including the information share approach of Hasbrouck (1995),[116] the component share methodology of Gonzalo and Granger (1995),[117] the information leadership approach of Yan and Zivot (2010),[118] and the information leadership share measure of Putnins (2013)[119] between the CME, CBOE, and spot prices using data sampled on a one-minute frequency. The authors find that price discovery is focused on the spot market. Similar evidence is presented by Baur and Dimpfl (2019),[120] where the authors use data sampled on a five-minute interval and conclude that price discovery occurs in the spot market.

On the other hand, a study by Kapar and Olmo (2019)[121] finds contradictory evidence using daily-sampled data, concluding that the CME futures market dominates price discovery based on the approaches of Gonzalo and Granger (1995) and Hasbrouck (1995). Similarly, Akyildirim et al. (2019)[122] show that Bitcoin futures play a significant role in price discovery relative to the spot market using the four previously mentioned measures of price discovery.

One potential reason for the mixed evidence, according to Hu et al. (2020)[123] is that cointegration relationships may go undetected if the underlying model formulation is constrained to be time-invariant. As such, the authors apply time-varying cointegrating coefficients based on the works of Park and Hahn (1999)[124] and Shi et al.(2018),[125] and conclude that futures prices Granger-cause spot prices and that futures prices dominate Bitcoin price discovery.

[115] Corbet S., Lucey B., Peat M., Vigne S. Bitcoin futures—What use are they? Economics Letters. 2018;172:23–27.

[116] Hasbrouck J. One security, many markets: Determining the contributions to price discovery. The Journal of Finance. 1995;50(4):1175–1199.

[117] Gonzalo J., Granger C. Estimation of common long-memory components in cointegrated systems. Journal of Business & Economic Statistics. 1995;13(1):27–35.

[118] Yan B., Zivot E. A structural analysis of price discovery measures. Journal of Financial Markets. 2010;13(1):1–19.

[119] Putniņš T.J. What do price discovery metrics really measure? Journal of Empirical Finance. 2013;23:68–83.

[120] Baur D.G., Dimpfl T. Price discovery in bitcoin spot or futures? Journal of Futures Markets. 2019;39(7):803–817.

[121] Kapar B., Olmo J. An analysis of price discovery between Bitcoin futures and spot markets. Economics Letters. 2019;174:62–64.

[122] Akyildirim E., Corbet S., Katsiampa P., Kellard N., Sensoy A. The development of bitcoin futures: Exploring the interactions between cryptocurrency derivatives. Finance Research Letters. 2019;34:1–9.

[123] Hu, Yang et al. ''What role do futures markets play in Bitcoin pricing? Causality, cointegration and price discovery from a time-varying perspective?.'' International Review of Financial Analysis vol. 72 (2020): 101569.

[124] Park J.Y., Hahn S.B. Cointegrating regressions with time varying coefficients. Econometric Theory. 1999;15(5):664–703.

[125] Shi S., Phillips P.C., Hurn S. Change detection and the causal impact of the yield curve. Journal of Time Series Analysis. 2018;39(6):966–987.

Additionally, the Bitcoin futures market is by orders of magnitude larger than the entire spot market of all cryptoassets in terms of traded volume. According to a study by the Blockchain Lab of Massachusetts Institute of Technology, ''the derivative market leads price discovery of bitcoin more frequently than the spot markets. The spot market is more likely to indicate the direction of the price movement while the derivatives market is more likely to lead the magnitude of the price movement'', says the report.[126]

The Bitcoin futures market has processed more than $1 trillion in futures volume per month since the start of the year. In November 2021, Bitcoin futures volume accounted for $1.58 trillion, while spot volume, in the same time frame, amounted to $1.4 trillion including both crypto-only and fiat currency volumes of all cryptoassets, not just Bitcoin. Namely, the Bitcoin futures market is 12% larger than the entire spot market in terms of volume just in the last month. Over the past three months, the average monthly spot volume was $1.3 trillion while the average Bitcoin futures volume was significantly greater (approximately 30%) than the spot at $1.71 trillion according to data from CryptoCompare and Coinglass.

In the past twelve months, the average monthly futures volume for Bitcoin was $1.89 trillion, while the monthly spot volume for all cryptoassets was $1.24 trillion. In other words, since the start of the year, the Bitcoin futures market is 52% larger than the spot volume of all cryptoassets traded on exchanges. As of December 2, the ratio of Bitcoin spot vs futures volume currently stands at 0.17. In other words, the Bitcoin spot market accounts for 17% of the bitcoin futures market in volume terms.

According to the Sponsor's research presented above, the CME Bitcoin Futures market is the leading market for bitcoin price formation. Where CME Bitcoin Futures lead the price in the spot market such that a potential manipulator of the bitcoin spot market (beyond just the constituents of the Index [127]) would have to participate in the CME Bitcoin Futures market, it follows that a potential manipulator of the Shares would similarly have to transact in the CME Bitcoin Futures market because the Index is based on spot prices.

Further, the Trust only allows for in-kind creation and redemption, which, as further described below, reduces the potential for manipulation of the Shares through manipulation of the Index or any of its individual constituents, again emphasizing that a potential manipulator of the Shares would have to manipulate the entirety of the bitcoin spot market, which is led by the CME Bitcoin Futures market. As such, the Exchange believes that part (a) of the significant market test outlined above is satisfied and that common membership in ISG between the Exchange and CME would assist the listing exchange in detecting and deterring misconduct in the Shares.

(b) Predominant Influence on Prices in Spot and Bitcoin Futures

The Exchange and Sponsor also believe that trading in the Shares would not be the predominant force on prices in the CME Bitcoin Futures market or spot market for a number of reasons, including the significant volume in the CME Bitcoin Futures market, the size of bitcoin's market cap, and the significant liquidity available in the spot market. Moreover, the fact that the Shares are created in-kind means that they are fully collateralized and should remain close to NAV given that investors and market makers would arbitrage any significant price deviations between the price of the Shares and prices in the spot market. In addition to the CME Bitcoin Futures market data points cited above, the spot market for bitcoin is also very liquid. According to data from CoinRoutes from February 2021, the cost to buy or sell $5 million worth of bitcoin averages roughly 10 basis points with a market impact of 30 basis points.[128] For a $10 million market order, the cost to buy or sell is roughly 20 basis points with a market impact of 50 basis points. Stated another way, a market participant could enter a market buy or sell order for $10 million of bitcoin and only move the market 0.5%. More strategic purchases or sales (such as using limit orders and executing through OTC bitcoin trade desks) would likely have less obvious impact on the market—which is consistent with MicroStrategy, Tesla, and Square being able to collectively purchase billions of dollars in bitcoin. As such, the combination of CME Bitcoin Futures leading price discovery, the overall size of the bitcoin market, and the ability for market participants, including authorized participants creating and redeeming in-kind with the Trust, to buy or sell large amounts of bitcoin without significant market impact will help prevent the Shares from becoming the predominant force on pricing in either the bitcoin spot or CME Bitcoin Futures markets, satisfying part (b) of the test outlined above.

(c) Other Means To Prevent Fraudulent and Manipulative Acts and Practices

As noted above, the Commission also permits a listing exchange to demonstrate that ''other means to prevent fraudulent and manipulative acts and practices'' are sufficient to justify dispensing with the requisite surveillance-sharing agreement. The Exchange and Sponsor believe that such conditions are present. According to the Sponsor, a significant portion of the considerations around Bitcoin pricing have historically stemmed from a lack of consistent pricing across markets. However, according to the Sponsor's research, cross-exchange spreads in Bitcoin have been declining consistently over the past several years. Based on the daily Bitcoin price series from several popular centralized exchanges [129] the Sponsor has calculated the largest cross-exchange percentage spread (labelled as %C-Spread) by deducting the highest or maximum price (P) at time t from the lowest or minimum, and dividing by the lowest across all exchanges (i). Formally, this is expressed as:

$$\%C - Spread_t = \frac{max(P_{i,t}) - min(P_{i,t})}{min(P_{i,t})}$$

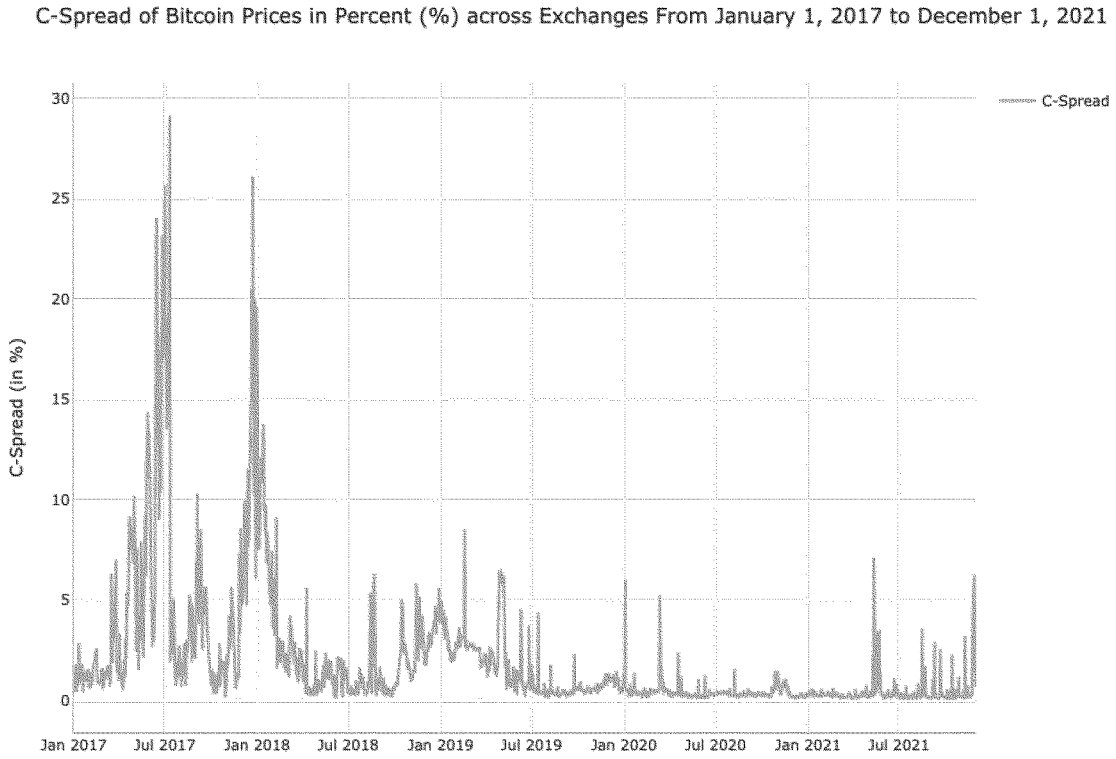
[126] Eguren, Luisa, Fondufe, Bryan, Hogan, Caleb, and Matthews, Claire. ''Price Discovery in the Bitcoin Spot and Derivatives Markets'' Massachusetts Institute of Technology Blockchain Lab Program, May 15th, 2020

[127] As further described below, the ''Index'' for the Fund is the S&P Bitcoin Index. The current exchange composition of the Index is Binance, Bitfinex, Bitflyer, Bittrex, Bitstamp, Coinbase Pro, Gemini, HitBTC, Huobi, Kraken, KuCoin, and Poloniex.

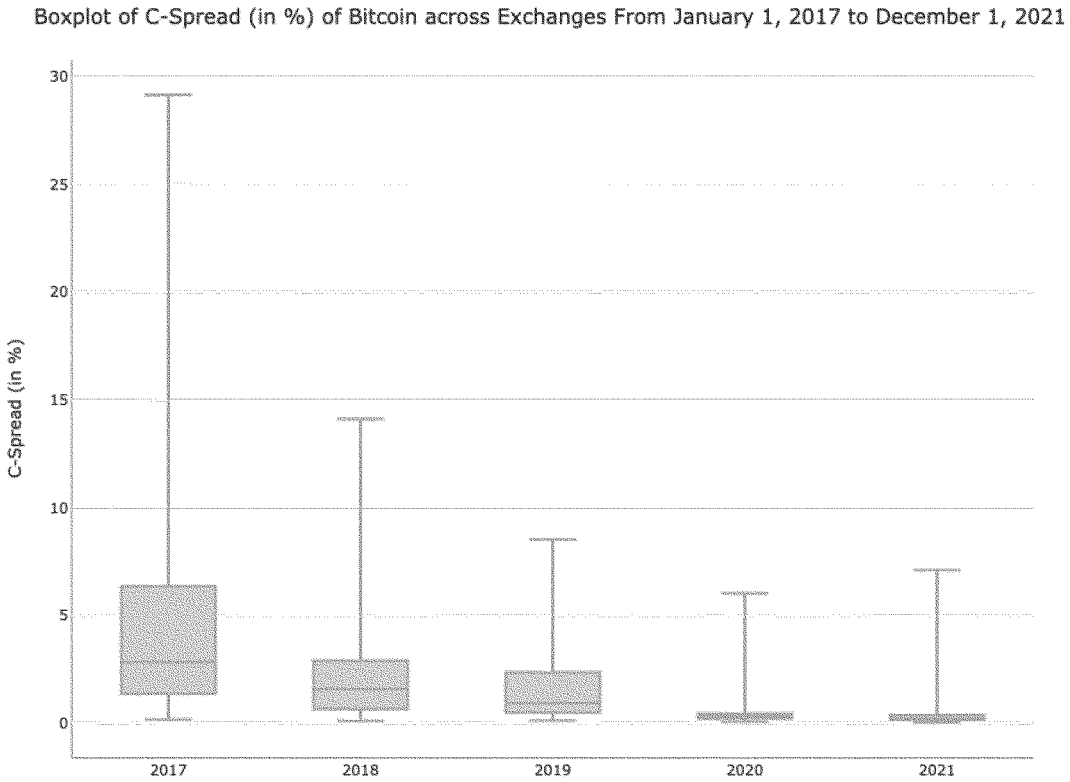
[128] These statistics are based on samples of bitcoin liquidity in USD (excluding stablecoins or Euro liquidity) based on executable quotes on Coinbase Pro, Gemini, Bitstamp, Kraken, LMAX Exchange, BinanceUS, and OKCoin during February 2021.

[129] The exchanges include Binance, Bitfinex, Bithumb, Bitstamp, Cexio, Coinbase, Coinone, Gateio, Gemini, HuobiPro, itBit, Kraken, Kucoin, and OKEX.

The results show a clear and sharp decline in the %C-Spread, indicating that the Bitcoin market has become more efficient as cross-exchange prices have converged over time.

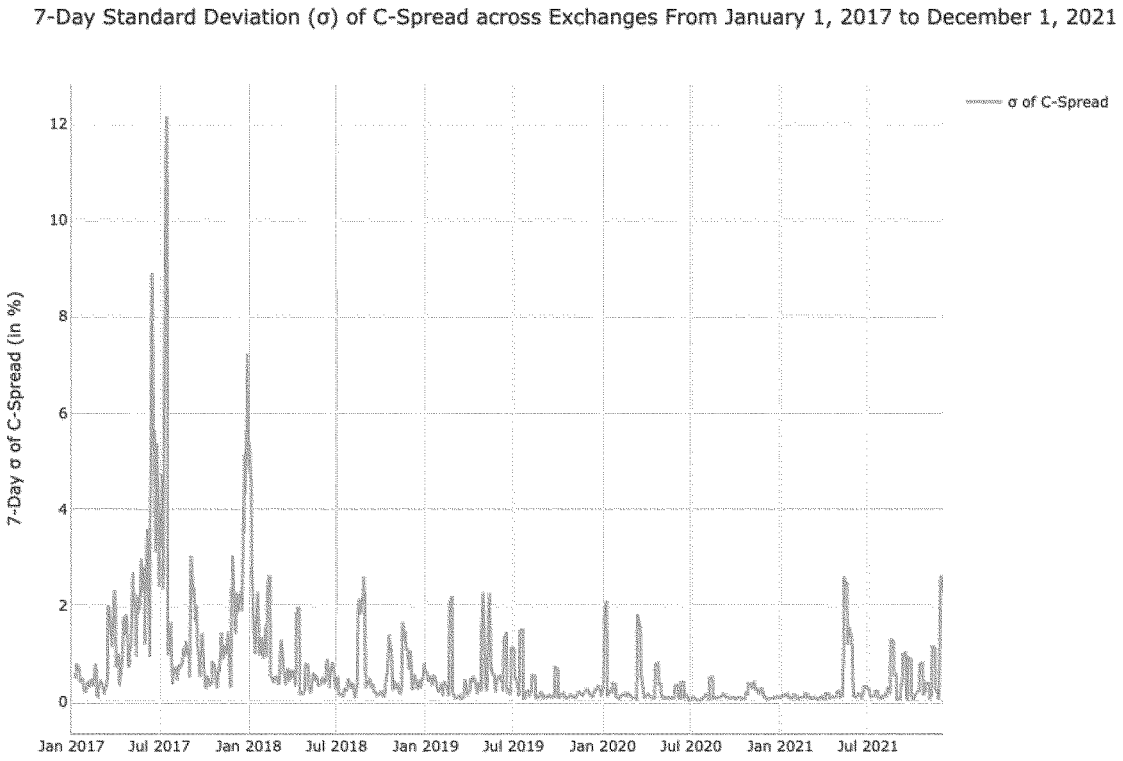


In addition, the magnitude of outlier % C-spreads has also declined over time. This boxplot shows that, not only did the median value of the %C-Spread decline over time, but also the extreme outlier values. For instance, the maximum %C-Spread for 2017, 2018, 2019, 2020, and 2021 are 29.14%, 14.45%, 8.54%, 6.04%, and 7.1%, respectively. The market has experienced a 38% year-on-year decline in the annual median %C-Spread indicating a greater degree of Bitcoin price convergence across exchanges and a more efficient market.

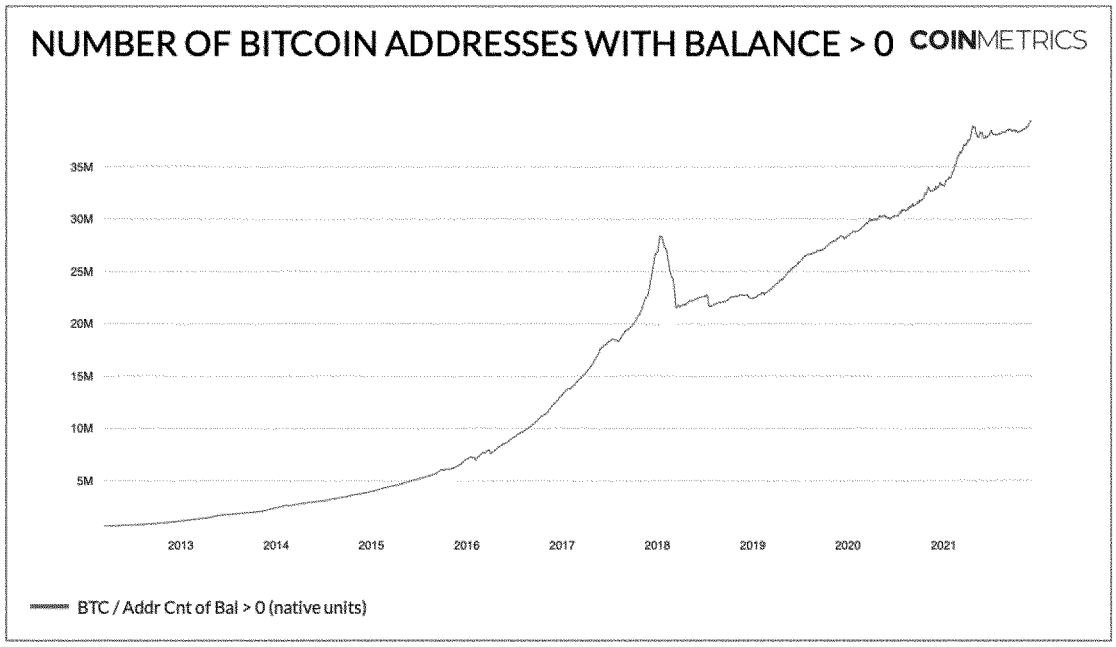


The dispersion (σ) of Bitcoin Prices has also declined over the same period. This chart shows the 7-day rolling standard deviation of the %C-Spread from January 1, 2017 to December 1, 2021. The Sponsor's research finds that the dispersion in Bitcoin prices across all exchanges has decreased over time, indicating that prices on all the considered exchanges converge towards the intrinsic average much more efficiently. This suggests that the market has become better at quickly reaching a consensus price for Bitcoin.

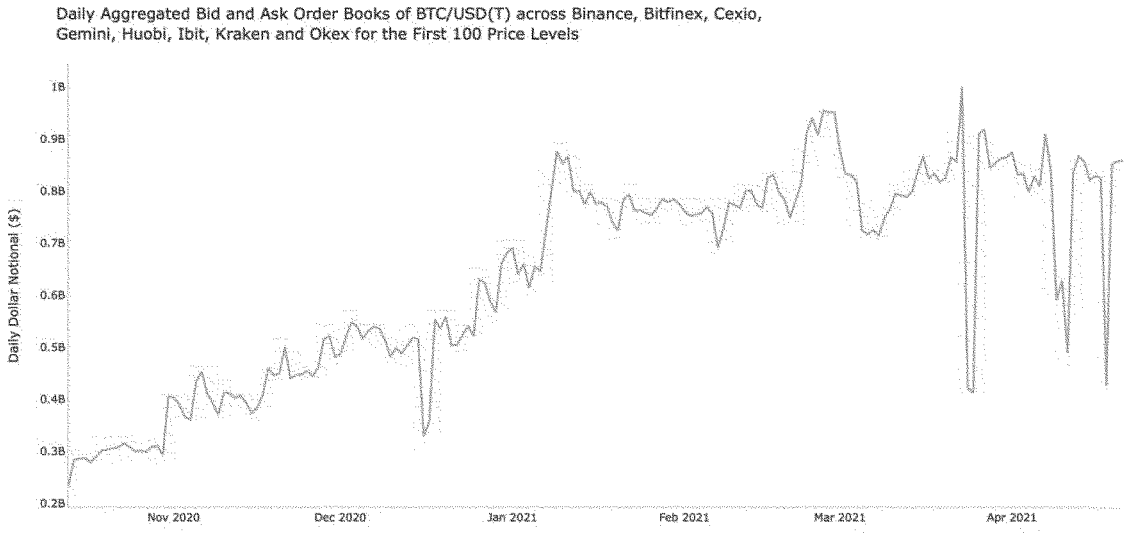
As the pricing of the crypto market becomes increasingly efficient, pricing methodologies become more accurate and less susceptible to manipulation. The clustering of prices across a variety of sources within the primary market points towards robust price discovery mechanisms and efficient arbitrage.



One factor that has contributed to the overall efficiency, price discovery, and lower volatility of the Bitcoin market is the increase in the number of participants, and subsequently, the total dollar amount allocated to this market. This can be illustrated by the following chart, which shows the number of wallet addresses holding Bitcoin from March 2012 to December 2021.



The increase in the number of participants has manifested itself in higher liquidity in the market. This is exhibited in the following chart, which shows the daily aggregated dollar notional of the bid and ask order books within the first 100 price levels across several of the largest centralized crypto exchanges from October 2020 to April 2021. Specifically, the dollar notional that is allocated closest to the mid price has increased from around $230 million to $860 million over that period, representing a 270% increase in half a year.

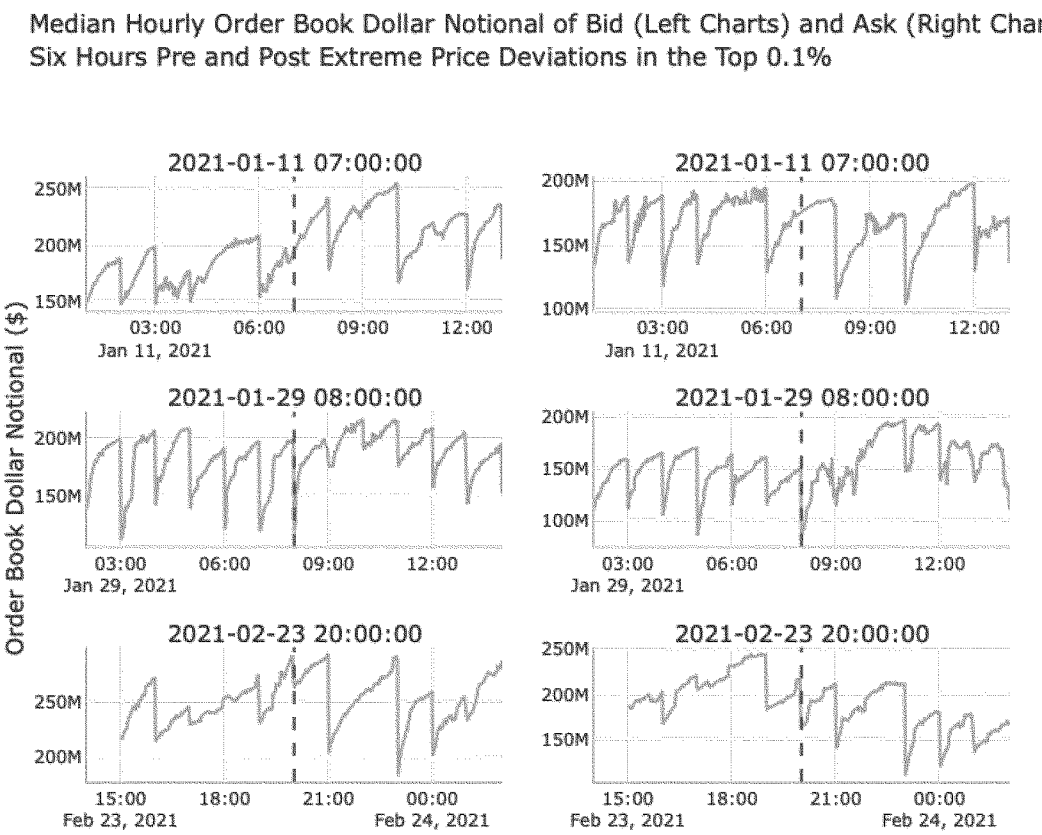


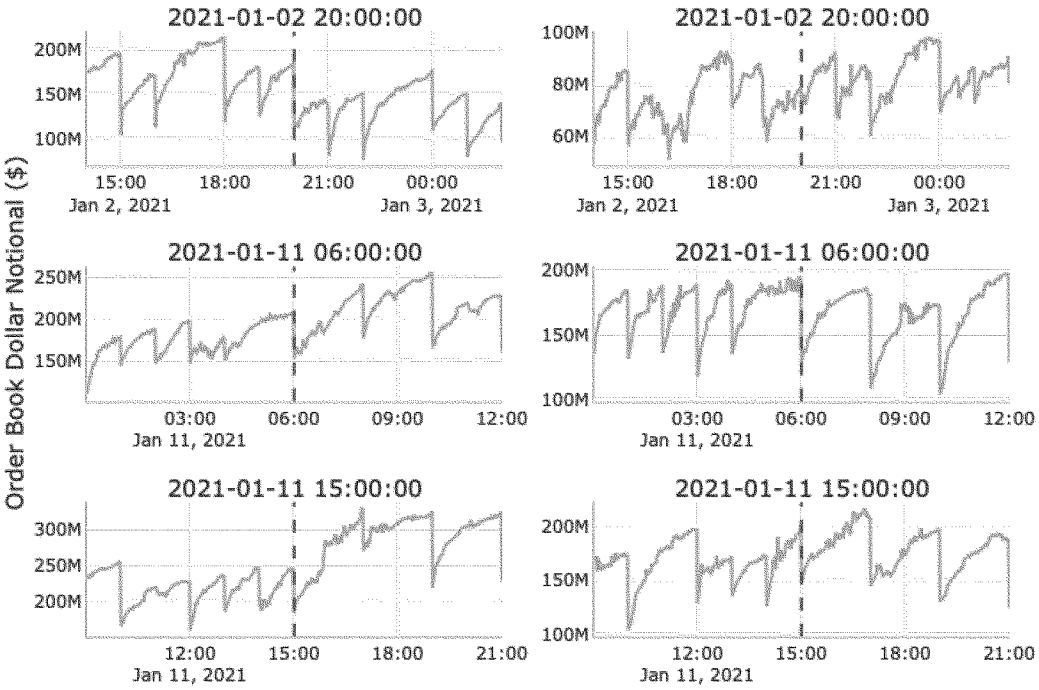
An increased notional order book suggests that there is a higher degree of consensus among investors regarding the price of Bitcoin. Moreover, this market characteristic hampers any attempt of price manipulation by any single large entity.

As a robustness check, the Sponsor investigates whether the dollar notional in the order book changes significantly prior to, and post an extreme price event. Specifically, for events constituting large increases in the price of Bitcoin, if the ask (or sell) side of the order book experiences a significant shrinkage in the dollar notional right before the event, then this may be an indication of market manipulation whereby the ask-side of the order book becomes sufficiently thin for a large order to move the price upward. Similarly, for events constituting large decreases in the price of Bitcoin, if the bid (or buy) side of the order book experiences a significant shrinkage in the dollar notional prior to such events, then this may be an indication of market manipulation whereby the thinner bid-side of the order book may potentially lead to significant downward price movements.

Using the top and bottom 0.1% of hourly price changes from October 2020 to April 2021 as events of extreme upward and downward market movements, respectively, the Sponsor plotted the bid (left charts) and ask (right charts) dollar notional of the Bitcoin order book within a six-hour window around these events in the chart below, which shows the results for extreme upward price movements. The extreme price events (indicated by the dashed green lines) perfectly coincide with the decrease in dollar notional of the ask-side of the order book. This is indicative of an efficient market, whereby large market movements are quickly and dynamically absorbed by a thick orderbook. Moreover, the dollar notional on the ask side after the event is replenished back to its pre-event level, which implies that market participants' reactions are quick to restore the market back to its equilibrium level.

The same results and conclusions are found for extreme downward price movements. The charts below show that such price events perfectly coincide with shrinkages on the bid side of the order book (left charts), indicating an efficient and dynamic Bitcoin market. Moreover, the bid-side of the order book after the event is also restored back to its pre-event level, which suggests that the market is symmetrically efficient in moving back to equilibrium.





Finally, offering only in-kind creation and redemption will provide unique protections against potential attempts to manipulate the Shares. While the Sponsor believes that the Index which it uses to value the Trust's bitcoin is

itself resistant to manipulation based on the methodology further described below, the fact that creations and redemptions are only available in-kind makes the manipulability of the Index significantly less important. Specifically, because the Trust will not accept cash to buy bitcoin in order to create new shares or, barring a forced redemption of the Trust or under other extraordinary circumstances, be forced to sell bitcoin to pay cash for redeemed shares, the price that the Sponsor uses to value the Trust's bitcoin is not particularly important.[130] When authorized participants are creating with the Trust, they need to deliver a certain number of bitcoin per share (regardless of the valuation used) and when they're redeeming, they can similarly expect to receive a certain number of bitcoin per share. As such, even if the price used to value the Trust's bitcoin is manipulated (which the Sponsor believes that its methodology is resistant to), the ratio of bitcoin per Share does not change and the Trust will either accept (for creations) or distribute (for redemptions) the same number of bitcoin regardless of the value. This not only mitigates the risk associated with potential manipulation, but also discourages and disincentivizes manipulation of the Index because there is little financial incentive to do so.

(ii) Designed To Protect Investors and the Public Interest

The Exchange believes that the proposal is designed to protect investors and the public interest. Over the past 1.5 years, U.S. investor exposure to bitcoin through OTC Bitcoin Funds has grown into the tens of billions of dollars and more than a billion dollars of exposure through Bitcoin Futures ETFs. With that growth, so too has grown the quantifiable investor protection issues to U.S. investors through roll costs for Bitcoin Futures ETFs and premium/discount volatility and management fees for OTC Bitcoin Funds. The Exchange believes that the concerns related to the prevention of fraudulent and manipulative acts and practices have been sufficiently addressed to be consistent with the Act and, to the extent that the Commission disagrees with that assertion, also believes that such concerns are now outweighed by these investor protection concerns. As such, the Exchange believes that approving this proposal (and comparable proposals) provides the Commission with the opportunity to allow U.S. investors with access to bitcoin in a regulated and transparent exchange-traded vehicle that would act to limit risk to U.S. investors by: (i) Reducing premium and discount volatility; (ii) reducing management fees through meaningful competition; (iii) reducing risks and costs associated with investing in Bitcoin Futures ETFs and operating companies that are imperfect proxies for bitcoin exposure; and (iv) providing an alternative to custodying spot bitcoin.

Commodity-Based Trust Shares

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed on the Exchange pursuant to the initial and continued listing criteria in Exchange Rule 14.11(e)(4). The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Commodity-Based Trust Shares. The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Trust or the Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Exchange Act, the Exchange will surveil for compliance with the continued listing requirements. If the Trust or the Shares are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12. The Exchange may obtain information regarding trading in the Shares and listed bitcoin derivatives via the ISG, from other exchanges who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement.

Availability of Information

The Exchange also believes that the proposal promotes market transparency in that a large amount of information is currently available about bitcoin and will be available regarding the Trust and the Shares. In addition to the price transparency of the Index, the Trust will provide information regarding the Trust's bitcoin holdings as well as additional data regarding the Trust. The Trust will provide an IIV per Share updated every 15 seconds, as calculated by the Exchange or a third-party financial data provider during the Exchange's Regular Trading Hours (9:30 a.m. to 4:00 p.m. E.T.). The IIV will be calculated by using the prior day's closing NAV per Share as a base and updating that value during Regular Trading Hours to reflect changes in the value of the Trust's bitcoin holdings during the trading day.

The IIV disseminated during Regular Trading Hours should not be viewed as an actual real-time update of the NAV, which will be calculated only once at the end of each trading day. The IIV will be widely disseminated on a per Share basis every 15 seconds during the Exchange's Regular Trading Hours by one or more major market data vendors. In addition, the IIV will be available through on-line information services.

The website for the Trust, which will be publicly accessible at no charge, will contain the following information: (a) The current NAV per Share daily and the prior business day's NAV and the reported closing price; (b) the BZX Official Closing Price in relation to the NAV as of the time the NAV is calculated and a calculation of the premium or discount of such price against such NAV; (c) data in chart form displaying the frequency distribution of discounts and premiums of the Official Closing Price against the NAV, within appropriate ranges for each of the four previous calendar quarters (or for the life of the Trust, if shorter); (d) the prospectus; and (e) other applicable quantitative information. The Trust will also disseminate the Trust's holdings on a daily basis on the Trust's website. The price of bitcoin will be made available by one or more major market data vendors, updated at least every 15 seconds during Regular Trading Hours. Information about the Index, including key elements of how the Index is calculated, will be publicly available at *https://www.spglobal.com/spdji/en/indices/digital-assets/sp-bitcoin-index/*.

The NAV for the Trust will be calculated by the Administrator once a day and will be disseminated daily to all market participants at the same time. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the CTA.

Quotation and last sale information for bitcoin is widely disseminated through a variety of major market data vendors, including Bloomberg and Reuters, as well as the Index. Information relating to trading, including price and volume information, in bitcoin is available from major market data vendors and from the exchanges on which bitcoin are traded.

[130] While the Index will not be particularly important for the creation and redemption process, it will be used for calculating fees.

Depth of book information is also available from bitcoin exchanges. The normal trading hours for bitcoin exchanges are 24 hours per day, 365 days per year

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change, rather will facilitate the listing and trading of an additional exchange-traded product that will enhance competition among both market participants and listing venues, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeBZX–2021–051 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2021–051. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBZX–2021–051, and should be submitted on or before January 18, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[131]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–27824 Filed 12–23–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93835; File No. SR–NYSEAMER–2021–45]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend Rule 904 (Position Limits)

December 20, 2021.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on December 6, 2021, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 904 (Position Limits) to increase position limits for options on certain exchange-traded funds. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 904 (Position Limits) to increase position limits for options on certain exchange-traded funds (''ETFs''). This is a competitive filing that is based on a proposal recently submitted by Cboe Exchange, Inc. (''Cboe'') and approved by the Securities and Exchange Commission (''Commission'').[4]

Position limits are designed to address potential manipulative schemes and adverse market impacts surrounding the use of options, such as disrupting the market in the security underlying the options. While position limits should address and discourage the potential for manipulative schemes and adverse market impact, if such limits are set too low, participation in the options market may be discouraged. The Exchange believes that position limits must therefore be balanced between mitigating concerns of any potential manipulation and the cost of inhibiting potential hedging activity that could be used for legitimate economic purposes.

[131] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 93525 (November 4, 2021), 86 FR 62584 (November 10, 2021) (Notice of Filing of Amendment Nos. 2 and 3 and Order Granting Accelerated Approval of SR–CBOE–2021–029).

In its filing, Cboe states that it has observed an ongoing increase in demand, for both trading and hedging purposes, in options on the following ETFs: (1) iShares iBoxx $ Investment Grade Corporate Bond ETF (''LQD'') and (2) VanEck Vectors Gold Miners ETF (''GDX''). Though the demand for these options appears to have increased, position limits for options on LQD and GDX have remained the same. The Exchange believes these unchanged position limits may have impeded, and may continue to impede, trading activity and strategies of investors, such as use of effective hedging vehicles or income generating strategies (*e.g.,* buy-write or put-write), and the ability of Market Makers to make liquid markets with tighter spreads in these options resulting in the transfer of volume to over-the-counter (''OTC'') markets. OTC transactions occur through bilateral agreements, the terms of which are not publicly disclosed to the marketplace. As such, OTC transactions do not contribute to the price discovery process on a public exchange or other lit markets. Therefore, the Exchange believes that the proposed increases in position limits for options on LQD and GDX may enable liquidity providers to provide additional liquidity to the Exchange and other market participants to transfer their liquidity demands from OTC markets to the Exchange. As described in further detail below, the Exchange believes that the continuously increasing market capitalization of LQD and GDX, including ETF components, as well as the highly liquid markets for each, reduces the concerns for potential market manipulation and/or disruption in the underlying markets upon increasing position limits, while the rising demand for trading options on LQD and GDX for legitimate economic purposes compels an increase in position limits.

Proposed Position Limits for Options on LQD and GDX

Position limits for options on ETFs are determined pursuant to Rule 904 and vary according to the number of outstanding shares and the trading volumes of the underlying equity security (which includes ETFs) over the past six months. Pursuant to Rule 904, the largest in capitalization and the most frequently traded stocks and ETFs have an option position limit of 250,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market; and smaller capitalization stocks and ETFs have position limits of 200,000, 75,000, 50,000 or 25,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market. Options on LQD and GDX are currently subject to the standard position limit of 250,000 contracts as set forth in Rule 904. Commentary .07(f) to Rule 904 sets forth separate, higher position limits for specific equity options (including options on specific ETFs).[5] The Exchange proposes to amend Commentary .07(f) to Rule 904 to increase the position limits and, as a result, exercise limits, for options on LQD and GDX.[6] The table below represents the current, and proposed, position limits for options on the ETFs subject to this proposal:

Product	Current position limit	Proposal position limit
LQD	250,000	500,000
GDX	250,000	500,000

The Exchange notes that the proposed position limit for options on LQD and GDX are consistent with current position limits for options on the iShares MSCI Brazil Capped ETF (''EWZ''), iShares 20+ Year Treasury Bond Fund ETF (''TLT''), iShares MSCI Japan ETF (''EWJ''), and iShares iBoxx High Yield Corporate Bond Fund (''HYG''). The Exchange represents that LQD and GDX qualify for either (1) the initial listing criteria set forth in Rule 915, Commentary .06 for ETFs holding non-U.S. component securities, or (2) the generic listing standards for series of portfolio depository receipts and index fund shares based on international or global indexes under which a comprehensive surveillance agreement (''CSA'') is not required, as well as (3) the continued listing criteria in Rule 916 (for ETFs).[7] In compliance with its listing rules, the Exchange also represents that non-U.S. component securities that are not subject to a CSA do not, in the aggregate, represent more than more than 50% of the weight of LQD and GDX.[8]

Composition and Growth Analysis for LQD and GDX

As stated above, position (and exercise) limits are intended to prevent the establishment of options positions that can be used to or potentially create incentives to manipulate the underlying market so as to benefit options positions. The Commission has recognized that these limits are designed to minimize the potential for mini-manipulations and for corners or squeezes of the underlying market, as well as serve to reduce the possibility for disruption of the options market itself, especially in illiquid classes.[9] LQD and GDX, as well as the ETF components, are highly liquid and are based on a broad set of highly liquid securities and other reference assets, as demonstrated through the trading statistics presented in this proposal. To support the proposed position limit increases, Cboe considered the liquidity of LQD and GDX, the value of LQD and GDX, their components and the relevant marketplace, the share and option volume for LQD and GDX, and, where applicable, the availability or comparison of economically equivalent products to options on LQD and GDX.

Cboe collected the following trading statistics regarding shares of and options on LQD and GDX and the values of LQD and GDX and their components:

[5] Adjusted option series, in which one option contract in the series represents the delivery of other than 100 shares of the underlying security as a result of a corporate action by the issuer of the security underlying such option series, do not impact the notional value of the underlying security represented by those options. When an underlying security undergoes a corporate action resulting in adjusted series, the Exchange lists new standard option series across all appropriate expiration months the day after the existing series are adjusted. The adjusted series are generally actively traded for a short period of time following adjustment, but orders to open options positions in the underlying security are almost exclusively placed in the new standard option series contracts.

[6] By virtue of Rule 905 (Exercise Limits), which is not being amended by this filing, the exercise limits for LQD and GDX options would be similarly increased, because Rule 905 provides that the exercise limits for index options and ETF options, respectively, are equivalent to their position limits.

[7] The Exchange notes that the initial listing criteria for options on ETFs that hold non-U.S. component securities are more stringent than the maintenance listing criteria for those same ETF options. *See* Rule 915, Commentary .06(a) (ii) and Rule 916, Commentary .07.

[8] *See* Rule 915, Commentary .06(a) (ii).

[9] *See* Securities Exchange Act Release No. 67672 (August 15, 2012), 77 FR 50750 (August 22, 2012) (SR–NYSEAmex–2012–29).

Product	ADV [10] (ETF shares) (millions)	ADV (option contracts)	Shares outstanding (millions) [11]	Fund market cap (USD) (millions) [12]	Share Value (USD)
LQD	14.1	30,300	308.1	54,113.7	130.13 (NAV)
GDX	39.4	166,000	419.8	16,170.5	33.80 (NAV)

Cboe also collected the same trading statistics, where applicable, as above regarding a sample of other ETFs, as well as the current position limits for options on such ETFs, to draw comparisons in support of proposed position limit increases for options on LQD and GDX (see further discussion below):

Product	ADV (ETF shares) (millions)	ADV (option contracts)	Shares outstanding (millions)	Fund market cap (USD) (millions)	Share value (USD)	Current position limits
EWZ	29.2	139,400	173.8	6,506.8	33.71 (NAV)	500,000
TLT	11.5	111,800	103.7	17,121.3	136.85 (NAV)	500,000
EWJ	8.2	15,500	185.3	13,860.7	69.72 (NAV)	500,000
HYG	30.5	261,600	254.5	24,067.5	86.86 (NAV)	500,000

The Exchange believes that, overall, the liquidity in the shares of LQD and GDX and in their overlying options, the larger market capitalizations for each LQD and GDX, and the overall market landscape relevant to each LQD and GDX support the proposal to increase the position limits for each option class. Given the robust liquidity in and value of LQD and GDX and their components, the Exchange does not anticipate that the proposed increase in position limits would create significant price movements as the relevant markets are large enough to adequately absorb potential price movements that may be caused by larger trades.

LQD tracks the performance of the Markit iBoxx USD Liquid Investment Grade (''IBOXIG'') Index, which is an index designed as a subset of the broader U.S. dollar-denominated corporate bond market which can be used as a basis for tradable products, such as ETFs, and is comprised of over 8,000 bonds.[13] The Exchange notes that from 2019 through 2020, ADV has grown significantly in shares of LQD and in options on LQD, from approximately 9.7 million shares in 2019 to 14.1 million through 2020, and from approximately 8,200 option contracts in 2019 to 30,300 through 2020. LQD also continued to experience significant growth in ADV in the first quarter of 2021 with an ADV of approximately 140,200 option contracts. Further, LQD generally experiences higher ADV in shares than both TLT (11.5 million shares) and EWJ (8.2 million shares) and almost double the ADV in option contracts than EWJ (15,500 option contracts). Options on each EWZ, TLT and EWJ are currently subject to a position limit of 500,000 contracts—the proposed limit for options on LQD. The NAV of LQD is also higher than, or comparable to, that of the NAV of the ETFs underlying the options that are currently subject to a position limit of 500,000 option contracts (as presented in the table above), which is indicative that the total value of its underlying components is generally higher or comparable. Per the tables above, LQD's total market capitalization of approximately $54.1 billion is also higher than or comparable to the total market capitalization of the ETFs underlying the options currently subject to a position limit of 5000,000 [sic] contracts. In addition to this, the Exchange notes that, although there are currently no options listed for trading on the IBOXIG Index, the components [14] of the IBOXIG Index, which can be used in creating a basket of securities that equate to the LQD ETF, are made up of over 8,000 bonds for which the outstanding face value of each must be greater than or equal to $2 billion.[15]

The Exchange believes that the total value of the bonds in the IBOXIG Index, coupled with LQD's share and option volume, total market capitalization, and NAV price indicates that the market is large enough to absorb potential price movements caused by a large trade in LQD. Also, as evidenced above, trading volume in LQD shares has increased over the past few years and the Exchange understands that market participants' need for options have continued to grow alongside the ETF. Particularly, the Exchange notes that in the last year, market participants have sought more cost-effective hedging strategies through the use of LQD options as a result of the borrow on other fixed income ETFs, such as HYG. Therefore, the Exchange believes that because LQD options are being increasingly utilized as an alternative to similar products, such as HYG options, then it is appropriate that options on LQD be subject to the same 500,000 contract position limit that currently exists for options on HYG.

GDX seeks to replicate as closely as possible the price and yield performance of the NYSE Arca Gold Miners (''GDMNTR'') Index, which is intended to track the overall performance of companies involved in the gold mining industry.[16] ADV in GDX options has increased from 2019 through 2020, with an ADV of

[10] Average daily volume (ADV) data for ETF shares and option contracts, as well as for ETF shares and options on the comparative ETFs presented below, are for all of 2020. Additionally, reference to ADV in ETF shares and ETF options, and indexes herein this proposal are for all of calendar year 2020, unless otherwise indicated.

[11] Shares Outstanding and Net Asset Values (''NAV''), as well as for the comparative ETFs presented below, are as of April 5, 2021 for all ETFs.

[12] Fund Market Capitalization data, as well as for the comparative ETFs presented below, are as of January 14, 2021.

[13] *See* Markit iBoxx USD Liquid Investment Grade Index, available at *https://cdn.ihsmarkit.com/www/pdf/MKT-iBoxx-USD-Liquid-Investment-Grade-Index-factsheet.pdf* (January 14, 2021).

[14] Investment grade corporate bonds.

[15] *See id.*

[16] *See* VanEck Vectors Gold Miners ETF, available at *https://www.vaneck.com/library/vaneck-vectors-etfs/gdx-fact-sheet-pdf* (January14, 2021).

approximately 117,400 option contracts in 2019 to an ADV of approximately 166,000 option contracts in 2020. The Exchange notes that ADV in GDX shares did not increase from 2019 to 2020. GDX options also experienced an ADV of approximately 287,800 option contracts in the first quarter of 2021. The Exchange notes that the ADV in GDX shares (39.4 million) and options on GDX (166,000 option contracts) are greater than the ADV in EWZ (29.2 million shares and 139,300 option contracts), TLT (11.5 million shares and 111,800 option contracts), EWJ (8.2 million shares and 15,500 option contracts) and HYG (30.5 million shares and 261,600 option contracts), each of which is currently subject to a position limit of 500,000 option contracts—the proposed limit for options on GDX. GDX also experiences a comparable, or higher, market capitalization (approximately $16.2 billion) than EWZ, TLT and EWZ. The Exchange particularly notes that many of the Brazil-based gold mining constituents included in GDX are also included in EWZ, which tracks the investment results of an index composed of Brazilian equities, and that the Exchange has not identified any issues with the continued listing and trading of EWZ options or any adverse market impact on EWZ in connection with the current 500,000 position limit in place for EWZ options. Additionally, like that of LQD above, there is currently no index option analogue for the GDX ETF on the GDMNTR Index approved for options trading, however, the components of the GDMNTR Index, which can be used to create the GDX ETF, currently must each have a market capitalization greater than $750 million, an ADV of at least 50,000 shares, and an average daily value traded of at least $1 million in order to be eligible for inclusion in the GDMNTR Index. The Exchange believes that the GDMNTR Index component inclusion requirements, as well as GDX's share and option volume and total market capitalization, indicate that the GDX market is sufficiently large and liquid enough to absorb price movements as a result of potentially oversized trades.

Creation and Redemption for ETFs

The Exchange believes that the creation and redemption process for the ETFs subject to this proposal will lessen the potential for manipulative activity with options on LQD and GDX. When an ETF provider wants to create more shares, it looks to an Authorized Participant (''AP'') (generally a Market Maker or other large financial institution) to acquire the underlying components the ETF is to hold. For instance, when an ETF is designed to track the performance of an index, the AP can purchase all the constituent securities in the exact same weight as the index, then deliver those shares to the ETF provider. In exchange, the ETF provider gives the AP a block of equally valued ETF shares, on a one-for-one fair value basis. The price is based on the NAV, not the market value at which the ETF is trading. The creation of new ETF units can be conducted during an entire trading day and is not subject to position limits. This process works in reverse where the ETF provider seeks to decrease the number of shares that are available to trade. The creation and redemption processes for LQD and GDX creates a direct link to the underlying components of the ETF and serves to mitigate potential price impact of the ETF shares that might otherwise result from increased position limits for the options on LQD and GDX.

The Exchange understands that the ETF creation and redemption processes seek to keep an ETF's share price trading in line with the product's underlying net asset value. Because an ETF trades like a stock, its share price will fluctuate during the trading day, due to simple supply and demand. If demand to buy an ETF is high, for instance, an ETF's share price might rise above the value of its underlying components. When this happens, the AP or issuer believes the ETF may now be overpriced, so it may buy shares of the component securities or assets and then sell ETF shares in the open market. This may drive the ETF's share price back toward the underlying net asset value. Likewise, if an ETF share price starts trading at a discount to the component securities or assets it holds, the AP or issuer can buy shares of the ETF and redeem them for the underlying components. Buying undervalued ETF shares may drive the share price of an ETF back toward fair value. This arbitrage process helps to keep an ETF's share price in line with the value of its underlying portfolio.

Surveillance and Reporting Requirements

The Exchange believes that increasing the position limits for the options on LQD and GDX would lead to a more liquid and competitive market environment for these options, which will benefit customers interested in trading these products. The reporting requirement for the options on LQD and GDX would remain unchanged. Thus, the Exchange would still require that each Member [17] that maintains positions in the options on the same side of the market, for its own account or for the account of a customer, report certain information to the Exchange. This information would include, but would not be limited to, the options' positions, whether such positions are hedged and, if so, a description of the hedge(s). Market Makers would continue to be exempt from this reporting requirement, however, the Exchange may access Market-Maker position information.[18] Moreover, the Exchange's requirement that Members file reports with the Exchange for any customer who held aggregate large long or short positions on the same side of the market of 200 or more option contracts of any single class for the previous day will remain at this level for the options subject to this proposal and will continue to serve as an important part of the Exchange's surveillance efforts.[19]

The Exchange believes that the existing surveillance procedures and reporting requirements at the Exchange and other SROs are capable of properly identifying disruptive and/or manipulative trading activity. The Exchange also represents that it has adequate surveillances in place to detect potential manipulation, as well as reviews in place to identify potential changes in composition of LQD and GDX and continued compliance with the Exchange's listing standards. These procedures utilize daily monitoring of market activity via automated surveillance techniques to identify unusual activity in both options and the underlyings, as applicable.[20] The Exchange also notes that large stock holdings must be disclosed to the Commission by way of Schedules 13D or 13G,[21] which are used to report ownership of stock which exceeds 5% of a company's total stock issue and may assist in providing information in

[17] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with an ATP. ATP Holders are deemed ''members'' under the Exchange Act. *See* Rule 900.2NY(5).

[18] The Options Clearing Corporation (''OCC'') through the Large option Position Reporting (''LOPR'') system acts as a centralized service provider for Member compliance with position reporting requirements by collecting data from each Member, consolidating the information, and ultimately providing detailed listings of each Member's report to the Exchange, as well as Financial Industry Regulatory Authority, Inc. (''FINRA''), acting as its agent pursuant to a regulatory services agreement (''RSA'').

[19] *See* Rule 906 for reporting requirements.

[20] The Exchange believes these procedures have been effective for the surveillance of trading the options subject to this proposal and will continue to employ them.

[21] 17 CFR 240.13d–1.

monitoring for any potential manipulative schemes.

The Exchange believes that the current financial requirements imposed by the Exchange and by the Commission adequately address concerns regarding potentially large, unhedged positions in the options on LQD and GDX. Current margin and risk-based haircut methodologies serve to limit the size of positions maintained by any one account by increasing the margin and/or capital that a Member must maintain for a large position held by itself or by its customer.[22] In addition, Rule 15c3–1 [23] imposes a capital charge on Members to the extent of any margin deficiency resulting from the higher margin requirement.

Non-Substantive Changes

The Exchange also proposes to make two non-substantive changes to remove the quotation marks around HYG and Financial Select Sector SPDR Fund (''XLF''), which would add internal consistency to the rule making it easier to navigate to the benefit of market participants.[24]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b) of the Act [25] in general, and furthers the objectives of Sections 6(b)(5) of the Act,[26] in that it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [27] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed increase in position limits for options on LQD and GDX will remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest, because it will provide market participants with the ability to more effectively execute their trading and hedging activities. The proposed increases will allow market participants to more fully implement hedging strategies in related derivative products and to further use options to achieve investment strategies (*e.g.,* there are other exchange-traded products (''ETPs'') that use options on the ETFs subject to this proposal as part of their investment strategy, and the applicable position limits as they stand today may inhibit these other ETPs in achieving their investment objectives, to the detriment of investors). Also, increasing the applicable position limits may allow Market Makers to provide the markets for these options with more liquidity in amounts commensurate with increased consumer demand in such markets. The proposed position limit increases may also encourage other liquidity providers to shift liquidity, as well as encourage consumers to shift demand, from OTC markets onto the Exchange, which will enhance the process of price discovery conducted on the Exchange through increased order flow.

In addition, the Exchange believes that the structure of LQD and GDX, the considerable market capitalization of the funds and underlying components, and the liquidity of the markets for the applicable options and underlying components will mitigate concerns regarding potential manipulation of the products and/or disruption of the underlying markets upon increasing the relevant position limits. As a general principle, increases in market capitalizations, active trading volume, and deep liquidity of the underlying components do not lead to manipulation and/or disruption. This general principle applies to the recently observed increased levels of market capitalization and trading volume and liquidity in shares of and options on LQD and GDX (as described above), and, as a result, the Exchange does not believe that the options markets or underlying markets would become susceptible to manipulation and/or disruption as a result of the proposed position limit increases. Indeed, the Commission has previously expressed the belief that not just increasing, but removing, position and exercise limits may bring additional depth and liquidity to the options markets without increasing concerns regarding intermarket manipulation or disruption of the options or the underlying securities.[28]

Further, the Exchange notes that the proposed rule change to increase position limits for select actively traded options is not novel and the Commission has approved similar proposed rule changes to increase position limits for options on similar, highly liquid and actively traded ETPs.[29] Furthermore, the Exchange again notes that that the proposed position limits for options on LQD and GDX are consistent with existing position limits for options on other ETFs in Rule 904, Commentary .07(f). The Exchange's surveillance and reporting safeguards continue to be designed to deter and detect possible manipulative behavior that might arise from increasing or eliminating position and exercise limits in certain classes. The Exchange believes that the current financial requirements imposed by the Exchange and by the Commission adequately address concerns regarding potentially large, unhedged position in the options on LQD and GDX, further promoting just and equitable principles of trading, the maintenance of a fair and orderly market, and the protection of investors.

Finally, the Exchange also proposes to make two non-substantive changes to remove the quotation marks around HYG and XLF, which would add internal consistency to the rule making it easier to navigate to the benefit of market participants.[30]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In this regard and as indicated above, the Exchange notes that the rule change is being proposed as a competitive response to a filing submitted by Cboe.[31]

The Exchange does not believe the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the increased position limits (and exercise limits) will be available to all market participants and apply to each in the same manner. The Exchange believes that the proposed rule change will provide additional opportunities for market participants to more efficiently achieve their investment and trading objectives.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the Act. On the contrary,

[22] *See* Exchange Rules, Section 9 for a description of margin requirements.

[23] 17 CFR 240.15c3–1.

[24] *See* proposed Commentary .07(f) to Rule 904.

[25] 15 U.S.C. 78f(b).

[26] 15 U.S.C. 78f(b)(5).

[27] *Id.*

[28] *See* Securities Exchange Act Release No. 62147 (October 28, 2005) (SR–CBOE–2005–41), at 62149.

[29] *See* Securities Exchange Act Release Nos. 88768 (April 29, 2020), 85 FR 26736 (May 5, 2020) (SR–CBOE–2020–015); 83415 (June 12, 2018), 83 FR 28274 (June 18, 2018) (SR–CBOE–2018–042); and 68086 (October 23, 2012), 77 FR 65600 (October 29, 2012) (SR–CBOE–2012–066).

[30] *See* proposed Commentary .07(f) to Rule 904.

[31] *See supra* note 4 (approval of Cboe filing).

the Exchange believes the proposal promotes competition because it may attract additional order flow from the OTC market to exchanges, which would in turn compete amongst each other for those orders. The Exchange believes market participants would benefit from being able to trade options with increased position limits in an exchange environment in several ways, including but not limited to the following: (1) Enhanced efficiency in initiating and closing out positions; (2) increased market transparency; and (3) heightened contra-party creditworthiness due to the role of OCC as issuer and guarantor. The Exchange notes that other options exchanges may choose to file similar proposals with the Commission to increase position limits on options on LQD and GDX.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [32] and Rule 19b–4(f)(6) thereunder.[33]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [34] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [35] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Exchange states that waiver of the operative delay would be consistent with the protection of investors and the public interest because it will ensure fair competition among the exchanges by allowing the Exchange to immediately increase the relevant position limits, which will provide consistency for Exchange Members that are also members at Cboe where these increased position limits are currently in place. The Commission notes that the Exchange's corresponding exercise limits for the options covered by this proposal also would be increased, consistent with the increased exercise limits for these options already in place at Cboe. For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal as operative upon filing.[36]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEAMER–2021–45 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2021–45. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2021–45, and should be submitted on or before January 18, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[37]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2021–27927 Filed 12–23–21; 8:45 am]

BILLING CODE 8011–01–P

[32] 15 U.S.C. 78s(b)(3)(A).

[33] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[34] 17 CFR 240.19b–4(f)(6).

[35] 17 CFR 240.19b–4(f)(6)(iii).

[36] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[37] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93833; File No. SR–NYSEArca-2021–105]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend Rule 6.8–O (Position Limits)

December 20, 2021.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on December 6, 2021, NYSE Arca, Inc. (''NYSE Arca''

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 6.8–O (Position Limits) to increase position limits for options on certain exchange-traded funds. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 6.8–O (Position Limits) to increase position limits for options on certain exchange-traded funds (''ETFs''). This is a competitive filing that is based on a proposal recently submitted by Cboe Exchange, Inc. (''Cboe'') and approved by the Securities and Exchange Commission (''Commission'').[4]

Position limits are designed to address potential manipulative schemes and adverse market impacts surrounding the use of options, such as disrupting the market in the security underlying the options. While position limits should address and discourage the potential for manipulative schemes and adverse market impact, if such limits are set too low, participation in the options market may be discouraged. The Exchange believes that position limits must therefore be balanced between mitigating concerns of any potential manipulation and the cost of inhibiting potential hedging activity that could be used for legitimate economic purposes.

In its filing, Cboe states that it has observed an ongoing increase in demand, for both trading and hedging purposes, in options on the following ETFs: (1) iShares iBoxx $ Investment Grade Corporate Bond ETF (''LQD'') and (2) VanEck Vectors Gold Miners ETF (''GDX''). Though the demand for these options appears to have increased, position limits for options on LQD and GDX have remained the same. The Exchange believes these unchanged position limits may have impeded, and may continue to impede, trading activity and strategies of investors, such as use of effective hedging vehicles or income generating strategies (*e.g.,* buy-write or put-write), and the ability of Market Makers to make liquid markets with tighter spreads in these options resulting in the transfer of volume to over-the-counter (''OTC'') markets. OTC transactions occur through bilateral agreements, the terms of which are not publicly disclosed to the marketplace. As such, OTC transactions do not contribute to the price discovery process on a public exchange or other lit markets. Therefore, the Exchange believes that the proposed increases in position limits for options on LQD and GDX may enable liquidity providers to provide additional liquidity to the Exchange and other market participants to transfer their liquidity demands from OTC markets to the Exchange. As described in further detail below, the Exchange believes that the continuously increasing market capitalization of LQD and GDX, including ETF components, as well as the highly liquid markets for each, reduces the concerns for potential market manipulation and/or disruption in the underlying markets upon increasing position limits, while the rising demand for trading options on LQD and GDX for legitimate economic purposes compels an increase in position limits.

Proposed Position Limits for Options on LQD and GDX

Position limits for options on ETFs are determined pursuant to Rule 6.8–O and vary according to the number of outstanding shares and the trading volumes of the underlying equity security (which includes ETFs) over the past six months. Pursuant to Rule 6.8–O, the largest in capitalization and the most frequently traded stocks and ETFs have an option position limit of 250,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market; and smaller capitalization stocks and ETFs have position limits of 200,000, 75,000, 50,000 or 25,000 contracts (with adjustments for splits, re-capitalizations, etc.) on the same side of the market. Options on LQD and GDX are currently subject to the standard position limit of 250,000 contracts as set forth in Rule 6.8–O. Commentary .06(f) to Rule 6.8–O sets forth separate, higher position limits for specific equity options (including options on specific ETFs).[5] The Exchange proposes to amend Commentary .06(f) to Rule 6.8–O to increase the position limits and, as a result, exercise limits, for options on LQD and GDX.[6] The table below represents the current, and proposed, position limits for options on the ETFs subject to this proposal:

Product	Current position limit	Proposal position limit
LQD	250,000	500,000
GDX	250,000	500,000

The Exchange notes that the proposed position limit for options on LQD and GDX are consistent with current position limits for options on the iShares MSCI Brazil Capped ETF (''EWZ''), iShares 20+ Year Treasury Bond Fund ETF (''TLT''), iShares MSCI Japan ETF (''EWJ''), and iShares iBoxx High Yield Corporate Bond Fund (''HYG''). The Exchange represents that LQD and GDX qualify for either (1) the initial listing criteria set forth in Rule 5.3–O(g)(2) for ETFs holding non-U.S. component securities, or (2) the generic listing standards for series of portfolio depository receipts and index fund shares based on international or global indexes under which a comprehensive surveillance agreement (''CSA'') is not

[4] *See* Securities Exchange Act Release No. 93525 (November 4, 2021), 86 FR 62584 (November 10, 2021) (Notice of Filing of Amendment Nos. 2 and 3 and Order Granting Accelerated Approval of SR–CBOE–2021–029).

[5] Adjusted option series, in which one option contract in the series represents the delivery of other than 100 shares of the underlying security as a result of a corporate action by the issuer of the security underlying such option series, do not impact the notional value of the underlying security represented by those options. When an underlying security undergoes a corporate action resulting in adjusted series, the Exchange lists new standard option series across all appropriate expiration months the day after the existing series are adjusted. The adjusted series are generally actively traded for a short period of time following adjustment, but orders to open options positions in the underlying security are almost exclusively placed in the new standard option series contracts.

[6] By virtue of Rule 6.9–O (Exercise Limits), which is not being amended by this filing, the exercise limits for LQD and GDX options would be similarly increased, because Rule 6.9–O provides that the exercise limits for index options and ETF options, respectively, are equivalent to their position limits.

required, as well as (3) the continued listing criteria in Rule 5.4–O (for ETFs).[7] In compliance with its listing rules, the Exchange also represents that non-U.S. component securities that are not subject to a CSA do not, in the aggregate, represent more than more than 50% of the weight of LQD and GDX.[8]

Composition and Growth Analysis for LQD and GDX

As stated above, position (and exercise) limits are intended to prevent the establishment of options positions that can be used to or potentially create incentives to manipulate the underlying market so as to benefit options positions. The Commission has recognized that these limits are designed to minimize the potential for mini-manipulations and for corners or squeezes of the underlying market, as well as serve to reduce the possibility for disruption of the options market itself, especially in illiquid classes.[9] LQD and GDX, as well as the ETF components, are highly liquid and are based on a broad set of highly liquid securities and other reference assets, as demonstrated through the trading statistics presented in this proposal. To support the proposed position limit increases, Cboe considered the liquidity of LQD and GDX, the value of LQD and GDX, their components and the relevant marketplace, the share and option volume for LQD and GDX, and, where applicable, the availability or comparison of economically equivalent products to options on LQD and GDX.

Cboe collected the following trading statistics regarding shares of and options on LQD and GDX and the values of LQD and GDX and their components:

Product	ADV [10] (ETF shares) (millions)	ADV (option contracts)	Shares outstanding (millions) [11]	Fund market cap (USD) (millions) [12]	Share value (USD)
LQD	14.1	30,300	308.1	54,113.7	130.13 (NAV)
GDX	39.4	166,000	419.8	16,170.5	33.80 (NAV)

Cboe also collected the same trading statistics, where applicable, as above regarding a sample of other ETFs, as well as the current position limits for options on such ETFs, to draw comparisons in support of proposed position limit increases for options on LQD and GDX (see further discussion below):[10] [11] [12]

Product	ADV (ETF shares) (millions)	ADV (option contracts)	Shares outstanding (millions)	Fund market cap (USD) (millions)	Share value (USD)	Current position limits
EWZ	29.2	139,400	173.8	6,506.8	33.71 (NAV)	500,000
TLT	11.5	111,800	103.7	17,121.3	136.85 (NAV)	500,000
EWJ	8.2	15,500	185.3	13,860.7	69.72 (NAV)	500,000
HYG	30.5	261,600	254.5	24,067.5	86.86 (NAV)	500,000

The Exchange believes that, overall, the liquidity in the shares of LQD and GDX and in their overlying options, the larger market capitalizations for each LQD and GDX, and the overall market landscape relevant to each LQD and GDX support the proposal to increase the position limits for each option class. Given the robust liquidity in and value of LQD and GDX and their components, the Exchange does not anticipate that the proposed increase in position limits would create significant price movements as the relevant markets are large enough to adequately absorb potential price movements that may be caused by larger trades.

LQD tracks the performance of the Markit iBoxx USD Liquid Investment Grade (''IBOXIG'') Index, which is an index designed as a subset of the broader U.S. dollar-denominated corporate bond market which can be used as a basis for tradable products, such as ETFs, and is comprised of over 8,000 bonds.[13] The Exchange notes that from 2019 through 2020, ADV has grown significantly in shares of LQD and in options on LQD, from approximately 9.7 million shares in 2019 to 14.1 million through 2020, and from approximately 8,200 option contracts in 2019 to 30,300 through 2020. LQD also continued to experience significant growth in ADV in the first quarter of 2021 with an ADV of approximately 140,200 option contracts. Further, LQD generally experiences higher ADV in shares than both TLT (11.5 million shares) and EWJ (8.2 million shares) and almost double the ADV in option contracts than EWJ (15,500 option contracts). Options on each EWZ, TLT and EWJ are currently subject to a position limit of 500,000 contracts—the proposed limit for options on LQD. The NAV of LQD is also higher than, or comparable to, that of the NAV of the ETFs underlying the options that are currently subject to a position limit of 500,000 option contracts (as presented in the table above), which is indicative that the total value of its underlying components is generally higher or comparable. Per the tables above, LQD's total market capitalization of approximately $54.1 billion is also higher than or comparable to the total market capitalization of the ETFs underlying the options currently

[7] The Exchange notes that the initial listing criteria for options on ETFs that hold non-U.S. component securities are more stringent than the maintenance listing criteria for those same ETF options. *See* Rules 5.3(g)(2) and 5.4–O(k).

[8] *See* Rule 5.3–O(g)(2)(B).

[9] *See* Securities Exchange Act Release No. 68001 (October 5, 2012), 77 FR 62303 (October 12, 2012) (SR–NYSEArca–2012–112).

[10] Average daily volume (ADV) data for ETF shares and option contracts, as well as for ETF shares and options on the comparative ETFs presented below, are for all of 2020. Additionally, reference to ADV in ETF shares and ETF options, and indexes herein this proposal are for all of calendar year 2020, unless otherwise indicated.

[11] Shares Outstanding and Net Asset Values (''NAV''), as well as for the comparative ETFs presented below, are as of April 5, 2021 for all ETFs.

[12] Fund Market Capitalization data, as well as for the comparative ETFs presented below, are as of January 14, 2021.

[13] *See* Markit iBoxx USD Liquid Investment Grade Index, available at *https://cdn.ihsmarkit.com/www/pdf/MKT-iBoxx-USD-Liquid-Investment-Grade-Index-factsheet.pdf* (January 14, 2021).

subject to a position limit of 5000,000 [sic] contracts. In addition to this, the Exchange notes that, although there are currently no options listed for trading on the IBOXIG Index, the components [14] of the IBOXIG Index, which can be used in creating a basket of securities that equate to the LQD ETF, are made up of over 8,000 bonds for which the outstanding face value of each must be greater than or equal to $2 billion.[15]

The Exchange believes that the total value of the bonds in the IBOXIG Index, coupled with LQD's share and option volume, total market capitalization, and NAV price indicates that the market is large enough to absorb potential price movements caused by a large trade in LQD. Also, as evidenced above, trading volume in LQD shares has increased over the past few years and the Exchange understands that market participants' need for options have continued to grow alongside the ETF. Particularly, the Exchange notes that in the last year, market participants have sought more cost-effective hedging strategies through the use of LQD options as a result of the borrow on other fixed income ETFs, such as HYG. Therefore, the Exchange believes that because LQD options are being increasingly utilized as an alternative to similar products, such as HYG options, then it is appropriate that options on LQD be subject to the same 500,000 contract position limit that currently exists for options on HYG.

GDX seeks to replicate as closely as possible the price and yield performance of the NYSE Arca Gold Miners (''GDMNTR'') Index, which is intended to track the overall performance of companies involved in the gold mining industry.[16] ADV in GDX options has increased from 2019 through 2020, with an ADV of approximately 117,400 option contracts in 2019 to an ADV of approximately 166,000 option contracts in 2020. The Exchange notes that ADV in GDX shares did not increase from 2019 to 2020. GDX options also experienced an ADV of approximately 287,800 option contracts in the first quarter of 2021. The Exchange notes that the ADV in GDX shares (39.4 million) and options on GDX (166,000 option contracts) are greater than the ADV in EWZ (29.2 million shares and 139,300 option contracts), TLT (11.5 million shares and 111,800 option contracts), EWJ (8.2 million shares and 15,500 option contracts) and HYG (30.5 million shares and 261,600 option contracts), each of which is currently subject to a position limit of 500,000 option contracts—the proposed limit for options on GDX. GDX also experiences a comparable, or higher, market capitalization (approximately $16.2 billion) than EWZ, TLT and EWZ. The Exchange particularly notes that many of the Brazil-based gold mining constituents included in GDX are also included in EWZ, which tracks the investment results of an index composed of Brazilian equities, and that the Exchange has not identified any issues with the continued listing and trading of EWZ options or any adverse market impact on EWZ in connection with the current 500,000 position limit in place for EWZ options. Additionally, like that of LQD above, there is currently no index option analogue for the GDX ETF on the GDMNTR Index approved for options trading, however, the components of the GDMNTR Index, which can be used to create the GDX ETF, currently must each have a market capitalization greater than $750 million, an ADV of at least 50,000 shares, and an average daily value traded of at least $1 million in order to be eligible for inclusion in the GDMNTR Index. The Exchange believes that the GDMNTR Index component inclusion requirements, as well as GDX's share and option volume and total market capitalization, indicate that the GDX market is sufficiently large and liquid enough to absorb price movements as a result of potentially oversized trades.

Creation and Redemption for ETFs

The Exchange believes that the creation and redemption process for the ETFs subject to this proposal will lessen the potential for manipulative activity with options on LQD and GDX. When an ETF provider wants to create more shares, it looks to an Authorized Participant (''AP'') (generally a Market Maker or other large financial institution) to acquire the underlying components the ETF is to hold. For instance, when an ETF is designed to track the performance of an index, the AP can purchase all the constituent securities in the exact same weight as the index, then deliver those shares to the ETF provider. In exchange, the ETF provider gives the AP a block of equally valued ETF shares, on a one-for-one fair value basis. The price is based on the NAV, not the market value at which the ETF is trading. The creation of new ETF units can be conducted during an entire trading day and is not subject to position limits. This process works in reverse where the ETF provider seeks to decrease the number of shares that are available to trade. The creation and redemption processes for LQD and GDX creates a direct link to the underlying components of the ETF and serves to mitigate potential price impact of the ETF shares that might otherwise result from increased position limits for the options on LQD and GDX.

The Exchange understands that the ETF creation and redemption processes seek to keep an ETF's share price trading in line with the product's underlying net asset value. Because an ETF trades like a stock, its share price will fluctuate during the trading day, due to simple supply and demand. If demand to buy an ETF is high, for instance, an ETF's share price might rise above the value of its underlying components. When this happens, the AP or issuer believes the ETF may now be overpriced, so it may buy shares of the component securities or assets and then sell ETF shares in the open market. This may drive the ETF's share price back toward the underlying net asset value. Likewise, if an ETF share price starts trading at a discount to the component securities or assets it holds, the AP or issuer can buy shares of the ETF and redeem them for the underlying components. Buying undervalued ETF shares may drive the share price of an ETF back toward fair value. This arbitrage process helps to keep an ETF's share price in line with the value of its underlying portfolio.

Surveillance and Reporting Requirements

The Exchange believes that increasing the position limits for the options on LQD and GDX would lead to a more liquid and competitive market environment for these options, which will benefit customers interested in trading these products. The reporting requirement for the options on LQD and GDX would remain unchanged. Thus, the Exchange would still require that each Member [17] that maintains positions in the options on the same side of the market, for its own account or for the account of a customer, report certain information to the Exchange. This information would include, but would not be limited to, the options' positions, whether such positions are hedged and, if so, a description of the hedge(s). Market Makers would continue to be exempt from this reporting requirement, however, the Exchange may access

[14] Investment grade corporate bonds.

[15] *See id.*

[16] *See* VanEck Vectors Gold Miners ETF, available at *https://www.vaneck.com/library/vaneck-vectors-etfs/gdx-fact-sheet-pdf* (January14, 2021).

[17] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with an OTP. OTP Holders and OTP Firms are deemed ''members'' under the Exchange Act. *See* Rule 1.1.

Market-Maker position information.[18] Moreover, the Exchange's requirement that Members file reports with the Exchange for any customer who held aggregate large long or short positions on the same side of the market of 200 or more option contracts of any single class for the previous day will remain at this level for the options subject to this proposal and will continue to serve as an important part of the Exchange's surveillance efforts.[19]

The Exchange believes that the existing surveillance procedures and reporting requirements at the Exchange and other SROs are capable of properly identifying disruptive and/or manipulative trading activity. The Exchange also represents that it has adequate surveillances in place to detect potential manipulation, as well as reviews in place to identify potential changes in composition of LQD and GDX and continued compliance with the Exchange's listing standards. These procedures utilize daily monitoring of market activity via automated surveillance techniques to identify unusual activity in both options and the underlyings, as applicable.[20] The Exchange also notes that large stock holdings must be disclosed to the Commission by way of Schedules 13D or 13G,[21] which are used to report ownership of stock which exceeds 5% of a company's total stock issue and may assist in providing information in monitoring for any potential manipulative schemes.

The Exchange believes that the current financial requirements imposed by the Exchange and by the Commission adequately address concerns regarding potentially large, unhedged positions in the options on LQD and GDX. Current margin and risk-based haircut methodologies serve to limit the size of positions maintained by any one account by increasing the margin and/or capital that a Member must maintain for a large position held by itself or by its customer.[22] In addition, Rule 15c3–1[23] imposes a capital charge on Members to the extent of any margin deficiency resulting from the higher margin requirement.

Non-Substantive Changes

The Exchange also proposes to make two non-substantive changes to remove the quotation marks around HYG and Financial Select Sector SPDR Fund (''XLF''), which would add internal consistency to the rule making it easier to navigate to the benefit of market participants.[24]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b) of the Act[25] in general, and furthers the objectives of Sections 6(b)(5) of the Act,[26] in that it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[27] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed increase in position limits for options on LQD and GDX will remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest, because it will provide market participants with the ability to more effectively execute their trading and hedging activities. The proposed increases will allow market participants to more fully implement hedging strategies in related derivative products and to further use options to achieve investment strategies (*e.g.,* there are other exchange-traded products (''ETPs'') that use options on the ETFs subject to this proposal as part of their investment strategy, and the applicable position limits as they stand today may inhibit these other ETPs in achieving their investment objectives, to the detriment of investors). Also, increasing the applicable position limits may allow Market Makers to provide the markets for these options with more liquidity in amounts commensurate with increased consumer demand in such markets. The proposed position limit increases may also encourage other liquidity providers to shift liquidity, as well as encourage consumers to shift demand, from OTC markets onto the Exchange, which will enhance the process of price discovery conducted on the Exchange through increased order flow.

In addition, the Exchange believes that the structure of LQD and GDX, the considerable market capitalization of the funds and underlying components, and the liquidity of the markets for the applicable options and underlying components will mitigate concerns regarding potential manipulation of the products and/or disruption of the underlying markets upon increasing the relevant position limits. As a general principle, increases in market capitalizations, active trading volume, and deep liquidity of the underlying components do not lead to manipulation and/or disruption. This general principle applies to the recently observed increased levels of market capitalization and trading volume and liquidity in shares of and options on LQD and GDX (as described above), and, as a result, the Exchange does not believe that the options markets or underlying markets would become susceptible to manipulation and/or disruption as a result of the proposed position limit increases. Indeed, the Commission has previously expressed the belief that not just increasing, but removing, position and exercise limits may bring additional depth and liquidity to the options markets without increasing concerns regarding intermarket manipulation or disruption of the options or the underlying securities.[28]

Further, the Exchange notes that the proposed rule change to increase position limits for select actively traded options is not novel and the Commission has approved similar proposed rule changes to increase position limits for options on similar, highly liquid and actively traded ETPs.[29] Furthermore, the Exchange again notes that that the proposed position limits for options on LQD and GDX are consistent with existing position limits for options on other ETFs in Commentary .06(f) to Rule 6.8–O. The Exchange's surveillance and reporting safeguards continue to be designed to deter and detect possible manipulative behavior that might arise

[18] The Options Clearing Corporation (''OCC'') through the Large option Position Reporting (''LOPR'') system acts as a centralized service provider for Member compliance with position reporting requirements by collecting data from each Member, consolidating the information, and ultimately providing detailed listings of each Member's report to the Exchange, as well as Financial Industry Regulatory Authority, Inc. (''FINRA''), acting as its agent pursuant to a regulatory services agreement (''RSA'').

[19] *See* Rule 6.6–O for reporting requirements.

[20] The Exchange believes these procedures have been effective for the surveillance of trading the options subject to this proposal and will continue to employ them.

[21] 17 CFR 240.13d–1.

[22] *See* Rule 4–O, Section 3 for a description of margin requirements.

[23] 17 CFR 240.15c3–1.

[24] *See* proposed Commentary .06(f) to Rule 6.8–O.

[25] 15 U.S.C. 78f(b).

[26] 15 U.S.C. 78f(b)(5).

[27] *Id.*

[28] *See* Securities Exchange Act Release No. 62147 (October 28, 2005) (SR–CBOE- 2005–41), at 62149.

[29] *See* Securities Exchange Act Release Nos. 88768 (April 29, 2020), 85 FR 26736 (May 5, 2020) (SR–CBOE–2020–015); 83415 (June 12, 2018), 83 FR 28274 (June 18, 2018) (SR–CBOE–2018–042); and 68086 (October 23, 2012), 77 FR 65600 (October 29, 2012) (SR–CBOE–2012–066).

from increasing or eliminating position and exercise limits in certain classes. The Exchange believes that the current financial requirements imposed by the Exchange and by the Commission adequately address concerns regarding potentially large, unhedged position in the options on LQD and GDX, further promoting just and equitable principles of trading, the maintenance of a fair and orderly market, and the protection of investors.

Finally, the Exchange also proposes to make two non-substantive changes to remove the quotation marks around HYG and XLF, which would add internal consistency to the rule making it easier to navigate to the benefit of market participants.[30]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In this regard and as indicated above, the Exchange notes that the rule change is being proposed as a competitive response to a filing submitted by Cboe.[31]

The Exchange does not believe the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the increased position limits (and exercise limits) will be available to all market participants and apply to each in the same manner. The Exchange believes that the proposed rule change will provide additional opportunities for market participants to more efficiently achieve their investment and trading objectives.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the Act. On the contrary, the Exchange believes the proposal promotes competition because it may attract additional order flow from the OTC market to exchanges, which would in turn compete amongst each other for those orders. The Exchange believes market participants would benefit from being able to trade options with increased position limits in an exchange environment in several ways, including but not limited to the following: (1) Enhanced efficiency in initiating and closing out positions; (2) increased market transparency; and (3) heightened contra-party creditworthiness due to the role of OCC as issuer and guarantor. The Exchange notes that other options exchanges may choose to file similar proposals with the Commission to increase position limits on options on LQD and GDX.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[32] and Rule 19b–4(f)(6) thereunder.[33]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[34] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[35] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Exchange states that waiver of the operative delay would be consistent with the protection of investors and the public interest because it will ensure fair competition among the exchanges by allowing the Exchange to immediately increase the relevant position limits, which will provide consistency for Exchange Members that are also members at Cboe where these increased position limits are currently in place. The Commission notes that the Exchange's corresponding exercise limits for the options covered by this proposal also would be increased, consistent with the increased exercise limits for these options already in place at Cboe. For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal as operative upon filing.[36]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2021–105 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2021–105. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than

[30] *See* proposed Commentary .06(f) to Rule 6.8–O.

[31] *See supra* note 4 (approval of Cboe filing).

[32] 15 U.S.C. 78s(b)(3)(A).

[33] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[34] 17 CFR 240.19b–4(f)(6).

[35] 17 CFR 240.19b–4(f)(6)(iii).

[36] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2021–105, and should be submitted on or before January 18, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[37]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2021–27925 Filed 12–23–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93829; File No. SR-CboeBZX–2021–084]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend its Fee Schedule

December 20, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 10, 2021, Cboe BZX Exchange, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'' or ''BZX Equities'') proposes to amend its Fee Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule as follows: (1) Modify the Add/Remove Volume Tiers, (2) adopt a new Non-Displayed Add Volume Tier, (3) modify Tier 2 of the Step-Up Tiers, and (4) eliminate the Total Volume Tier. The Exchange proposes to implement the proposed change to its fee schedule on December 1, 2021.[3]

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues that do not have similar self-regulatory responsibilities under the Exchange Act, to which market participants may direct their order flow. Based on publicly available information,[4] no single registered equities exchange has more than 16% of the market share. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. The Exchange in particular operates a ''Maker-Taker'' model whereby it pays credits to Members that add liquidity and assesses fees to those that remove liquidity. The Exchange's fee schedule sets forth the standard rebates and rates applied per share for orders that provide and remove liquidity, respectively. Additionally, in response to the competitive environment, the Exchange also offers tiered pricing which provides Members opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

Add/Remove Volume Tiers

Pursuant to footnote 1 of the Fee Schedule, the Exchange currently offers Add/Remove Volume Tiers (tiers 1 through 5) that provide Members an opportunity to receive an enhanced rebate from the standard rebate for liquidity adding orders that yield fee codes B,[5] V,[6] and Y[7] and meet certain required volume-based criteria. Specifically, the Tiers are as follows:

- Tier 1 offers an enhanced rebate of $0.0025 per share for qualifying orders (*i.e.,* yielding fee codes B, V, or Y) where a Member has an ADAV[8] as a percentage of TCV[9] equal to or greater than 0.08% or where a Member has an ADAV equal to or greater than 8 million shares.
- Tier 2 offers an enhanced rebate of $0.0027 per share for qualifying orders (*i.e.,* yielding fee codes B, V, or Y) where a Member has an ADAV as a percentage of TCV equal to or greater than 0.15% or where a Member has an ADAV equal to or greater than 15 million shares.
- Tier 3 offers an enhanced rebate of $0.0029 per share for qualifying orders (*i.e.,* yielding fee codes B, V, or Y) where a Member has an ADAV as a percentage of TCV equal to or greater than 0.35%

[37] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed fee changes on December 1, 2021 (SR–BZX–2021–081). On December 10, 2021, the Exchange withdrew that filing and submitted this proposal.

[4] See Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (November 24, 2021), available at *https://markets.cboe.com/us/equities/market_statistics/.*

[5] Orders yielding Fee Code ''B'' are displayed orders adding liquidity to BZX (Tape B).

[6] Orders yielding Fee Code ''V'' are displayed orders adding liquidity to BZX (Tape A).

[7] Orders yielding Fee Code ''Y'' are displayed orders adding liquidity to BZX (Tape C).

[8] ''ADAV'' means average daily added volume calculated as the number of shares added per day and ''ADV'' means average daily volume calculated as the number of shares added or removed, combined, per day. ADAV and ADV are calculated on a monthly basis.

[9] ''TCV'' means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply.

or where a Member has an ADAV equal to or greater than 35 million shares.

• Tier 4 offers an enhanced rebate of $0.0030 per share for qualifying orders (*i.e.,* yielding fee codes B, V, or Y) where a Member has an ADAV as a percentage of TCV equal to or greater than 0.60% or where a Member has an ADAV equal to or greater than 60 million shares.

• Tier 5 offers an enhanced rebate of $0.0031 per share for qualifying orders (*i.e.,* yielding fee codes B, V, or Y) where a Member has an ADAV as a percentage of TCV equal to or greater than 1.00% or where a Member has an ADAV equal to or greater than 100 million shares.

The Exchange now proposes to modify existing Tiers 1 and 2, add a new Tier 2, and renumber existing Tiers 2 through 5. Specifically, as proposed the Tiers would provide for the following:

• Proposed Tier 1 would offer an enhanced rebate of $0.0020 per share (instead of $0.0025 per share) for qualifying orders (*i.e.,* yielding fee codes B, V, or Y) where a Member has an ADAV as a percentage of TCV equal to or greater than 0.08% [sic] or where a Member has an ADAV equal to or greater than 10 million shares (instead of 8 million shares).

• Proposed Tier 2 would offer an enhanced rebate of $0.0025 per share for qualifying orders (*i.e.,* yielding fee codes B, V, or Y) where a Member has an ADAV as a percentage of TCV equal to or greater than 0.20% or where a Member has an ADAV equal to or greater than 20 million shares.

• Proposed Tier 3 (current Tier 2) would offer an enhanced rebate of $0.0027 per share for qualifying orders (*i.e.,* yielding fee codes B, V, or Y) where a Member has an ADAV as a percentage of TCV equal to or greater than 0.25% (instead of 0.15%) or where a Member has an ADAV equal to or greater than 25 million shares (instead of 15 million).

• Proposed Tiers 4 through 6 would have the same criteria and provide the same enhanced rebate as existing Tiers 3 through 5, respectively. The only proposed change is to modify the Tier numbers of Tier 3 through 5 to Tier 4 through 6, respectively.

Although the proposed changes to the thresholds of proposed Tiers 1 and 3 result in more stringent criteria, Members still have an opportunity to receive an enhanced rebate if they meet the applicable tier threshold. Moreover, the proposed changes are designed to encourage Members to increase their displayed liquidity in Tape A, B and C securities on the Exchange, thereby contributing to a deeper and more liquid market, which benefits all market participants and provides greater execution opportunities on the Exchange.

Non-Displayed Add Volume Tiers

Pursuant to footnote 1 of the Fee Schedule, the Exchange currently offers Non-Displayed Add Volume Tiers (tiers 1 through 4) that provide Members an opportunity to receive an enhanced rebate from the standard rebate for liquidity adding orders that yield fee codes HB,[10] HV,[11] and HY [12] and meet certain required volume-based criteria. Specifically, the Add Volume Tiers are as follows:

• Non-Displayed Add Volume Tier 1 offers an enhanced rebate of $0.0018 per share for qualifying orders (*i.e.,* yielding fee codes HB, HI,[13] HV, or HY) where a Member adds an ADV equal to or greater than 0.05% of the TCV.

• Non-Displayed Add Volume Tier 2 offers an enhanced rebate of $0.0020 per share for qualifying orders (*i.e.,* yielding fee codes HB, HI, HV, or HY) where a Member adds an ADV equal to or greater than 0.10% of the TCV.

• Non-Displayed Add Volume Tier 3 offers an enhanced rebate of $0.0025 per share for qualifying orders (*i.e.,* yielding fee codes HB, HI, HV, or HY) where a Member adds an ADV equal to or greater than 0.15% of the TCV.

• Non-Displayed Add Volume Tier 4 offers an enhanced rebate of $0.0029 per share for qualifying orders (*i.e.,* yielding fee codes HB, HI, HV, or HY) where a Member adds an ADV equal to or greater than 0.35% of the TCV.

Now, the Exchange proposes to introduce a new Non-Displayed Add Volume Tier 4 and renumber existing Non-Displayed Add Volume Tier 4 to Tier 5. Specifically, proposed Non-Displayed Add Volume Tier 4 is as follows:

• Proposed Non-Displayed Add Volume Tier 4 offers an enhanced rebate of $0.00275 per share for qualifying orders (*i.e.,* yielding fee codes HB, HI, HV, or HY) where a Member adds an ADV equal to or greater than 0.20% of the TCV.

The proposed change is designed to give Members an additional opportunity to receive an enhanced rebate for orders meeting the applicable threshold. Further, the proposed change is designed to encourage Members to increase their non-displayed volume adding liquidity on the Exchange, contributing to a deeper and more liquid market, which benefits all market participants and provides greater execution opportunities on the Exchange.

Step-Up Tiers

Pursuant to footnote 2 of the Fee Schedule, the Exchange currently offers Step-Up Tiers (tiers 1 and 2) that provide Members an opportunity to receive an enhanced rebate from the standard rebate for liquidity adding orders that yield fee codes B, V, and Y where they increase their relative liquidity each month over a predetermined baseline. Tier 2 of the Step-Up Tiers provides an enhanced rebate of $0.0032 per share to a Member that (1) has a Step-Up Add TCV [14] from June 2021 equal to or greater than 10 million shares; and (2) has an ADV equal to or greater than 0.30% of the TCV or the Member has an ADV equal to or greater than 35 million. The Exchange notes that step-up tiers are designed to encourage Members that provide displayed liquidity on the Exchange to increase their order flow, which would benefit all Members by providing greater execution opportunities on the Exchange. Now the Exchange proposes to amend criteria (1) of the current criteria for Step-Up Tier 2 to provide an alternative means of satisfying the first prong. Particularly, the Exchange proposes to provide under criteria (1) that a Member must have a Step-Up ADAV from June 2021 equal to or greater than 10 million shares or, alternatively, a Member must have a Step-Up Add TCV from June 2021 equal to or greater than 0.10%. The Exchange believes that the tier as proposed will further incentivize increased order flow to the Exchange, which may contribute to a deeper, more liquid market to the benefit of all market participants by creating a more robust and well-balanced market ecosystem. Step-Up Tier 2, as modified, continues to be available to all Members and would provide Members an opportunity to receive an enhanced rebate.

Total Volume Tiers

The Exchange also proposes to eliminate the Total Volume Tier 1, which is the only Tier under Total Volume Tiers and is currently described under footnote 3 of the fee schedule. Particularly, this tier applies to orders yielding fee code B, V, or Y and

[10] Orders yielding Fee Code ''HB'' are non-displayed orders adding liquidity to BZX (Tape B).

[11] Orders yielding Fee Code ''HV'' are non-displayed orders adding liquidity to BZX (Tape A).

[12] Orders yielding Fee Code ''HY'' are non-displayed orders adding liquidity to BZX (Tape C).

[13] Orders yielding Fee Code ''HI'' are non-displayed orders adding liquidity to BZX that receive price improvement.

[14] ''Step-Up Add TCV'' means ADAV as a percentage of TCV in the relevant baseline month subtracted from current ADAV as a percentage of TCV.

provides a $0.0033 per share rebate to Members that have an ADV greater than or equal to 1.40% of the TCV. No Member has reached this tier in several months and the Exchange therefore no longer wishes to, nor is it required to, maintain such a tier.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Securities Exchange Act of 1934 (the ''Act''),[15] in general, and furthers the objectives of Section 6(b)(4) and 6(b)(5),[16] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members, issuers and other persons using its facilities. The Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The proposed rule changes reflect a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members, and thus is in the public interest. The Exchange notes that relative volume-based incentives and discounts have been widely adopted by exchanges, including the Exchange, and are reasonable, equitable and non-discriminatory because they are open to all members on an equal basis and provide additional benefits or discounts that are reasonably related to (i) the value to an exchange's market quality and (ii) associated higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns. Additionally, as noted above, the Exchange operates in highly competitive market. The Exchange is only one of several equity venues to which market participants may direct their order flow, and it represents a small percentage of the overall market. It is also only one of several maker-taker exchanges. Competing equity exchanges offer similar tiered pricing structures, including schedules of rebates and fees that apply based upon members achieving certain volume and/or growth thresholds, as well as assess similar fees or rebates for similar types of orders, to that of the Exchange. These competing pricing schedules, moreover, are presently comparable to those that the Exchange provides, including the pricing of comparable criteria and/or fees and rebates.

The Exchange believes the proposed changes to the Add/Remove Volume Tiers, Non-Displayed Add Volume Tiers, and Step-Up Tiers are reasonable because each tier, as modified, continues to be available to all Members and provide Members an opportunity to receive an enhanced rebate. The Exchange also believes that the proposed enhanced rebates continue to be commensurate with the proposed criteria. That is, the rebates reasonably reflect the difficulty in achieving the applicable criteria as amended. The Exchange believes the proposed changes to the Add/Remove Volume Tiers, Non-Displayed Add Volume Tiers, and Step-Up Tiers represent an equitable allocation of rebates and is not unfairly discriminatory because all Members are eligible for those tiers and would have the opportunity to meet a tier's criteria and would receive the proposed rebate if such criteria is met. Without having a view of activity on other markets and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would definitely result in any Members qualifying for the proposed tier. While the Exchange has no way of predicting with certainty how the proposed tiers will impact Member activity, the Exchange anticipates that at least five Members will be able to satisfy the criteria proposed under the Add/Remove Volume Tier 1, one Member will be able to satisfy the criteria proposed under the Add/Remove Volume Tier 3, one Member will be able to satisfy the criteria proposed under the Non-Displayed Tier 4, and one Member will be able to satisfy the criteria proposed under the Step-Up Tier 2. The Exchange does not expect any Member to immediately satisfy the criteria proposed under the Add Volume Tier 2; however, the Exchange believes the proposed rebate incentivizes Members to meet the tier's criteria in the future. The Exchange also notes that proposed tier/rebate will not adversely impact any Member's ability to qualify for other reduced fee or enhanced rebate tiers. Should a Member not meet the proposed criteria under the modified tier, the Member will merely not receive that corresponding enhanced rebate.

Finally, the Exchange believes the proposed amendment to remove the Total Volume Tier is reasonable because no Member has achieved this tier in several months. Moreover, the Exchange is not required to maintain this tier and Members still have a number of other opportunities and a variety of ways to receive enhanced rebates for displayed liquidity, including the enhanced rebates under the Add Volume Tiers under footnote 1 of the fees schedule. The Exchange believes the proposal to eliminate this tier is also equitable and not unfairly discriminatory because it applies to all Members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional order flow to a public exchange, thereby promoting market depth, execution incentives and enhanced execution opportunities, as well as price discovery and transparency for all Members. As a result, the Exchange believes that the proposed changes further the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [17]

The Exchange believes the proposed rule changes do not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed tier changes apply to all Members equally in that all Members continue to be eligible for the Add Volume, Non-Displayed Add Volume, and Step-Up Tiers, have a reasonable opportunity to meet the tiers' criteria and will receive the corresponding additional rebates if such criteria are met. Additionally, the proposed tier changes are designed to attract additional order flow to the Exchange. The Exchange believes that the updated tier criteria would incentivize market participants to direct liquidity adding order flow to the Exchange, bringing with it additional execution opportunities for market participants and improved price transparency. Greater overall order flow, trading opportunities, and pricing transparency benefits all market participants on the Exchange by enhancing market quality and continuing to encourage Members to send orders, thereby contributing towards a robust and well-balanced market ecosystem.

Next, the Exchange believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in

[15] 15 U.S.C. 78f.

[16] 15 U.S.C. 78f(b)(4) and (5).

[17] Securities Exchange Act Release No. 51808, 70 FR 37495, 37498–99 (June 29, 2005) (S7–10–04) (Final Rule).

furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow, including 15 other equities exchanges and off exchange venues and alternative trading systems. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single equities exchange has more than 16% [18] of the market share. Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [19] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission*, the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . ..''.[20] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

[18] Supra note 3.

[19] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[20] *NetCoalition* v. *SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [21] and paragraph (f) of Rule 19b–4 [22] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeBZX–2021–084 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2021–084. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBZX–2021–084 and should be submitted on or before January 18, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2021–27922 Filed 12–23–21; 8:45 am]

BILLING CODE 8011–01–P

[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b–4(f).

[23] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 11587]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Paintings on Stone: Science and the Sacred 1530–1800'' 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 ''Paintings on Stone: Science and the Sacred 1530–1800'' at the Saint Louis Art Museum, in Saint Louis, Missouri, 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: Chi D. Tran, Program Administrator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@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), E.O. 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, and Delegation of Authority No. 236–3 of August 28, 2000, and the Delegation of Functions and Authorities signed by the Assistant Secretary for Educational and Cultural Affairs on December 16, 2021.

Stacy E. White,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2021–28175 Filed 12–23–21; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 11586]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Frédéric Bruly Bouabré: World Unbound'' 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 ''Frédéric Bruly Bouabré: World Unbound'' at The Museum of Modern Art, New York, New York, 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: Chi D. Tran, Program Administrator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@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), E.O. 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, and Delegation of Authority No. 236–3 of August 28, 2000, and the Delegation of Functions and Authorities signed by the Assistant Secretary for Educational and Cultural Affairs on December 16, 2021.

Stacy E. White,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2021–28183 Filed 12–23–21; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

Privacy Act of 1974; System of Records

ACTION: Notice of a new system of records.

AGENCY: Surface Transportation Board.

SUMMARY: This system will allow the Surface Transportation Board (STB) to collect, maintain and track records on employees and applicants for employment with disabilities who requested or received reasonable accommodation from the STB, and to allow the STB to collect, maintain and track records on employees who requested or received religious accommodations from the STB.

DATES: Please submit comments on or before January 14, 2022. This new system is effective upon publication in today's **Federal Register**, with the exception of the routine uses, which are effective January 14, 2022.

ADDRESSES: Address comments concerning this notice to Marquis Toson, Privacy Officer, *privacy@stb.gov.* Comments may also be sent to Marquis Toson, Privacy Officer, Surface Transportation Board, 395 E Street SW, Washington, DC 20423, (202) 245–0458 (Fax).

FOR FURTHER INFORMATION CONTACT: Marquis Toson, Surface Transportation Board, 395 E Street, SW, Washington, DC 20423, (202) 245–0458 (Fax), *privacy@stb.gov.*

SUPPLEMENTARY INFORMATION: Under the Privacy Act of 1974 (5 U.S.C. 552a), as amended, Federal agencies are required to publish a system of records notice in the **Federal Register** informing the public of any new or modified system of records maintained by the agency and searched by personal identifier. The following notice describes a new system of records.

SYSTEM NAME AND NUMBER:

Religious and Disability Reasonable Accommodation Records within the Office 365 MT system.

SECURITY CLASSIFICATION:

Unclassified

SYSTEM LOCATION:

395 E Street SW, Washington, DC 20423, Office 365 MT is a multi-tenant cloud computing-based subscription service offering from Microsoft.

SYSTEM MANAGER(S):

Greg Marzetta, Surface Transportation Board, 395 E Street SW, Suite 1027.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Rehabilitation Act of 1973; 29 U.S.C. Section 701 *et seq.* Americans with Disabilities Act (ADA) as amended; 42 U.S.C. 12101 *et seq.* Title VII of the Civil Rights Act of 1964; 42 U.S.C. 2000e *et seq*. Executive Order 13164 (July 28, 2000).

PURPOSE(S) OF THE SYSTEM:

To allow the STB to collect, maintain and track records on current and former employees and applicants for employment with disabilities, who request and receive reasonable accommodation, as required by Sections 501, 504, and 701 of the Rehabilitation Act of 1973 and the ADA Amendments Act of 2008. In addition, to allow the STB to collect, maintain and track records on current and former employees and applicants and applicants who request religious accommodation as required by Title VII of the Civil Rights Act of 1964. The system will track the receipt, processing and disposition of requests for disability accommodation and religious accommodation to comply with applicable laws and regulations and to preserve and maintain confidentiality.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former Surface Transportation Board employees and applicants for employment at the Surface Transportation Board.

CATEGORIES OF RECORDS IN THE SYSTEM:

Case number, name, accommodation requested, date of request, job position, office/division, accommodation type, impairment, disability type, description of religious belief and/or practices, and case notes.

RECORD SOURCE CATEGORIES:

Information in this system comes from the employee/applicant to whom it applies (or their representative), members of the STB Reasonable

Accommodation Advisory Panel, an employee's supervisor, other required STB personnel and/or the treating physician(s) or medical institution.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to the disclosures permitted under subsection (b) of the Privacy Act, the STB may disclose information contained in this system of records without the consent of the subject individual, if the disclosure is compatible with the purpose for which the records was collected under the following routine uses:

a. A record from this system of records may be disclosed as a routine use to provide information to OPM and/or MSPB for review, audit, or reporting purposes;

b. A record from this system of records that indicates a violation of civil or criminal law regulation or order may be referred as a routine use to a Federal, State, or local agency that has authority to investigate, enforce, implement or prosecute such laws;

c. A record from this system of records may be disclosed as a routine use to a Federal, State, or local agency, to obtain information relevant to an STB decision concerning hiring or retaining an employee, letting a contract, or issuing a security clearance, license, grant or other benefit;

d. A record from this system of records may be disclosed as a routine use, if it is relevant and necessary, in the course of discovery; in presenting evidence to a court, magistrate, administrative tribunal, or grand jury or pursuant to a qualifying order from any of those; in alternative dispute resolution proceedings, such as arbitration or mediation; or in the course of settlement negotiations;

e. A record from this system of records may be disclosed as a routine use to a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual;

f. A record from this system of records may be disclosed as a routine use to STB experts or consultants, and those under contract with the STB on a ''need-to-know'' basis for a purpose within the scope of an STB task. This access will be granted to an STB contractor or employee of such contractor by a system manager only after satisfactory justification has been provided to the system manager;

g. A record from this system of records may be disclosed as a routine use to appropriate agencies, entities, and persons when (1) STB suspects or has confirmed that there has been a breach of the systems of records, (2) STB has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, STB (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 STB efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm; and

h. A record from this system of records may be disclosed as a routine use to another Federal agency or Federal entity, when the STB 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 individual, 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:

Electronic records are stored on a secure server. Sensitive or confidential paper records are stored in a secured room or filing cabinet.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by employee/requester name or case number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retained under the National Archives and Records Administration's General Records Schedule 2.3: Employee Relations Records; 020 Reasonable Accommodation Case Files, Temporary. Destroy 3 years after employee separation from the agency or all appeals are concluded whichever is later, but longer retention is authorized if required for business use.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Only personnel with a ''need to know'' are authorized to access the records. Network access to electronic records is generally controlled by PIV-enabled or password-enabled authenticated user and limited according to job function. Additionally, access to the electronic records is only available from STB government furnished equipment. Access to hard-copy records is controlled by lock and key or by access to a secure area and is limited according to job function and ''need to know''.

RECORD ACCESS PROCEDURES:

Same as ''Notification Procedures''

CONTESTING RECORD PROCEDURES:

Same as ''Notification Procedures''

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether this system of records contains information about them should write to the Freedom of Information Act or Privacy Act Officer at Surface Transportation Board, 395 E Street SW, Washington, DC 20423, (202) 245–0458 (Fax), *privacy@stb.gov.*

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Dated: December 21, 2021.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2021–28022 Filed 12–23–21; 8:45 am]

BILLING CODE 4915–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Correction: Modification of U.S. Tariff-Rate Quotas and the Harmonized Tariff Schedule of the United States

AGENCY: Office of the United States Trade Representative.

ACTION: Correction.

SUMMARY: The U.S. Trade Representative published a notice in the **Federal Register** on July 6, 2021 (July 6 notice), modifying the Harmonized Tariff Schedule of the United States (HTSUS) to divide certain U.S. tariff-rate quotas (TRQs) currently allocated to the European Union (EU), between the EU and the United Kingdom (UK) as a result of Brexit and to reflect changes in the composition of the EU. This notice corrects an error in the July 6 notice in paragraph 5 of the section titled *Modification of the HTSUS.* The operative language of paragraph 5 is not affected.

DATES: The changes made by the July 6 notice, as modified by this correction, are applicable as of January 1, 2022.

FOR FURTHER INFORMATION CONTACT: Joan E. Hurst, Office of Agricultural Affairs, at 202–395–6117, or *Joan_E_Hurst@ustr.eop.gov.*

SUPPLEMENTARY INFORMATION: In the July 6 notice (86 FR 35560), the U.S. Trade

Representative divided the TRQs allocated to the EU under Additional U.S. Notes 6 and 16 to 18 to chapter 4 and Additional U.S. Note 5(a) to chapter 24 of the HTSUS between the EU and the UK according to the average percentage of in-quota imports for the 2013–2015 period, and determined that the UK will have access to a specific in-quota quantity under these notes.

The Office of the United States Trade Representative (USTR) has become aware of a ministerial error in paragraph 5 of the section of the notice titled *Modification of the HTSUS.* This paragraph indicates that Additional U.S. Note 5(a) to chapter 24 of the HTSUS is to be modified, in part, by deleting the quantity ''10,000'' in the Quantity (metric tons) column for the EU27 and inserting the quantity ''9,956'' in the Quantity (metric tons) column for the EU27 in lieu thereof. USTR is correcting this paragraph to indicate that Additional U.S. Note 5(a) to chapter 24 of the HTSUS is to be modified, in part, by deleting the quantity ''10,000'' in the Quantity (metric tons) column for the European Community and inserting the quantity ''9,956'' in the Quantity (metric tons) column for the European Community in lieu thereof.

For ease of reference, the entirety of the changes, as corrected by this notice, is published below:

Modification of the HTSUS

Effective with respect to articles entered for consumption, or withdrawn from warehouse for consumption, on or after January 1, 2022:

1. Additional U.S. Note 2 to chapter 4 of the HTSUS is modified by: (a) Inserting ''Croatia,'' into the list of countries in alphabetical order; and (b) deleting ''the Slovak Republic, Sweden or the United Kingdom'' and inserting ''the Slovak Republic or Sweden'' in lieu thereof.

2. Additional U.S. Note 16 to chapter 4 of the HTSUS is modified by: (a) Inserting ''United Kingdom'' into the list of countries in alphabetical order; (b) inserting a quota quantity of ''2,213,374'' in the Quantity (kg) column for the United Kingdom; (c) deleting the quantity ''27,846,224'' in the Quantity (kg) column for the EU27; and (d) inserting ''25,632,850'' in the Quantity (kg) column for the EU27 in lieu thereof.

3. Additional U.S. Note 17 to chapter 4 of the HTSUS is modified by: (a) Inserting ''United Kingdom'' into the list of countries in alphabetical order; (b) inserting a quota quantity of ''23,617'' in the Quantity (kg) column for the United Kingdom; (c) deleting the quantity ''2,829,000'' in the Quantity (kg) column for the EU27; and (d) inserting ''2,805,383'' in the Quantity (kg) column for the EU27 in lieu thereof.

4. Additional U.S. Note 18 to chapter 4 of the HTSUS is modified by: (a) inserting ''United Kingdom'' into the list of countries in alphabetical order; (b) inserting a quota quantity of ''895,948'' in the Quantity (kg) column for the United Kingdom; (c) deleting the quantity ''1,313,000'' in the Quantity (kg) column for the EU27; and (d) inserting ''417,052'' in the Quantity (kg) column for the EU27 in lieu thereof.

5. Additional U.S. Note 5(a) to chapter 24 of the HTSUS is modified by: (a) Deleting ''Spain, Sweden, and the United Kingdom'' and inserting ''Spain, and Sweden'' in lieu thereof; (b) inserting ''United Kingdom'' in the list of countries in alphabetical order; (c) inserting a quota quantity of ''44'' in the Quantity (metric tons) column for the United Kingdom; (d) deleting the quantity ''10,000'' in the Quantity (metric tons) column for the European Community; and (e) inserting the quantity ''9,956'' in the Quantity (metric tons) column for the European Community in lieu thereof.

Modification of the TRQ Allocation for Butter and Fresh or Sour Cream Containing Over 45 Percent by Weight of Butterfat

The U.S. Department of Agriculture annually publishes in the **Federal Register** the country allocations for Additional U.S. Note 6 to chapter 4 in appendices 1 and 2, pursuant to the Dairy Tariff-Rate Quota Import Licensing Regulation, 7 CFR part 6. With respect to the published in-quota quantity of 96,161 kilograms allocated to the EU 27 for the TRQ in Additional U.S. Note 6 to chapter 4 of the HTSUS, the U.S. Trade Representative has determined that, effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after January 1, 2022, the UK shall have access to a quantity of not less than 14,062 kilograms and the EU 27 shall have access to a quantity of not less than 82,099 kilograms.

Greta Peisch,

General Counsel, Office of the United States Trade Representative.

[FR Doc. 2021–27938 Filed 12–23–21; 8:45 am]

BILLING CODE 3290–F2–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No.: FAA–2021–1199: Notice No. NOA–183–21–01]

Agency Information Collection Activities: Requests for Comments; Renewed Approval of Information Collection; Approval of Information Collection: Organization Designation Authorization

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. This collection involves organizations applying to perform certification functions on behalf of the FAA, including approving data and issuing various aircraft and organization certificates. The information will be used to determine an applicant's qualifications to perform functions as a representative of the FAA Administrator and to authorize organizations to perform those functions.

DATES: Written comments should be submitted by February 25, 2022.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: Scott Geddie, Section Manager, Compliance Systems Section, AIR–634, Systems Policy Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 6500 S MacArthur Blvd., ARB Building, Room 304, Oklahoma City, OK 73169.

FOR FURTHER INFORMATION CONTACT: Scott Geddie, Section Manager, Compliance Systems Section telephone 405–954–6897; *scott.geddie@faa.gov.*

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0704.

Title: Organization Designation Authorization.

Form Numbers: FAA Form 8100–13.

Type of Review: Extension without change of an information collection.

Background: 49 U.S.C. 44702(d) authorizes the Administrator of the Federal Aviation Administration to delegate to any properly qualified private person functions related to the examination, inspection, and testing necessary to the issuance of certificates. Title 14 of Code of Federal Regulations (CFR) Part 183, Subpart D allows the FAA to appoint organizations as

Administrator representatives. As authorized, these organizations perform certification functions on behalf of the FAA. Applications include information about the applicant, the applicant's experience and qualifications, and the authority it seeks. Applications are submitted to the appropriate FAA office responsible for delegating the issuance certificates and approvals and are reviewed by the FAA team assigned to the applicant to determine whether the applicant meets the requirements necessary to be authorized as a representative of the Administrator. Procedures manuals are submitted for applications that are accepted by the FAA and contain the applicant's proposed procedures to be approved by the FAA to ensure that the correct processes are utilized when performing functions on behalf of the FAA as required by part 183 subpart D. These requirements are necessary to manage the various approvals issued by the organization and document approvals issued and must be maintained to address potential future safety issues.

Respondents: This collection involves organizations applying to perform certification functions on behalf of the FAA.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 43.5 hours.

Estimated Total Annual Burden: 5,623 hours.

Issued in Oklahoma City, OK, on December 21, 2021.

Scott A. Geddie,

Manager, Compliance Systems, Systems Policy Branch, AIR–630, Policy and Innovation Division.

[FR Doc. 2021–28055 Filed 12–23–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2021–0269]

Privacy Act of 1974; Department of Transportation, Maritime Administration; DOT/MARAD 035; United States Merchant Marine Academy (USMMA) Student Religious Accommodations Files

AGENCY: Maritime Administration, Transportation (DOT).

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Maritime Administration (MARAD) intends to establish a new system of records for the United States Merchant Marine Academy (USMMA) entitled ''DOT/MARAD 035—USMMA Student Religious Accommodations Files.'' This system allows MARAD/USMMA to collect, use, maintain, and disseminate the records needed to process, manage, maintain, and resolve reasonable accommodation requests from USMMA students and accepted applicants based on religious belief, practice, or observance. This includes requests for accommodation to decline vaccinations. The information will be used to make determinations for exemptions to vaccination requirements. MARAD/USMMA is required to consider reasonable accommodation requests in accordance with applicable law including the Religious Freedom Restoration Act and Executive Order 13160, Nondiscrimination on the Basis of Race, Sex, Color, National Origin, Disability, Religion, Age, Sexual Orientation, and Status as a Parent in Federally Conducted Education and Training Programs.

DATES: This new system of records is effective upon publication; however, comments on the Routine Uses will be accepted on or before January 26, 2022. The Routine Uses will become effective at the close of the comment period. MARAD may publish an amended System of Records Notice (SORN) in light of any comments received.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2021–0269 by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Search ''MARAD–2021–0269'' and follow the instructions for submitting comments.
- *Email: Rulemakings.MARAD@dot.gov.* Include ''MARAD–2021–0269'' in the subject line of the message.
- *Mail/Hand-Delivery/Courier:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, Washington, DC 20590. If you would like to know that your comments reached the facility, please enclose a stamped, self-addressed postcard or envelope. The Docket Management Facility is open 9:00 a.m. to 5:00 p.m., Monday through Friday, except on Federal holidays.

You may view the public comments submitted on this rulemaking at *www.regulations.gov.*

When searching for comments, please use the Docket ID: MARAD–2021–0269. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *www.FederalRegister.gov* and the Government Publishing Office's website at *www.GovInfo.gov.*

Note: If you mail or hand-deliver your input, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission. If you submit your inputs by mail or hand-delivery, they must be submitted in an unbound format, no larger than 8 ½ by 11 inches, single-sided, suitable for copying and electronic filing.

Instructions: All submissions received must include the agency name and docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: For general and privacy questions, please contact Karyn Gorman, Acting Departmental Chief Privacy Officer, Department of Transportation, S–83, Washington, DC 20590, Email: *privacy@dot.gov,* Tel. (202) 366–3140.

SUPPLEMENTARY INFORMATION:

Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, MARAD is proposing a new system of records entitled ''DOT/MARAD 035—USMMA Student Religious Accommodations Files.'' Executive Order 13160, Nondiscrimination on the Basis of Race, Sex, Color, National Origin, Disability, Religion, Age, Sexual Orientation, and Status as a Parent in Federally Conducted Education and Training Programs and the Religious Freedom Restoration Act (RFRA)], 42 U.S.C. 2000bb *et seq.,* require MARAD/USMMA to provide religious accommodations in some circumstances. MARAD/USMMA is required to collect information on religious accommodation requests to determine eligibility for religious accommodations, and grant or deny accommodation or exemption for such a request. This system will collect information related to individuals requesting religious exemptions from vaccines or other accommodations necessary for the free exercise of religion. By requesting a religious accommodation, individuals are authorizing MARAD/USMMA to collect and maintain a record of information pertaining to the exercise of religious beliefs protected by the First Amendment.

In order to make a determination regarding religious accommodation, the USMMA must collect information from the accepted applicant or student applying for accommodation. The information contained within this system of records will be collected directly from individual USMMA students and accepted applicants who are the subject of the record. This new system will be included in MARAD's inventory of record systems.

MARAD has also included DOT General Routine Uses, to the extent they are compatible with the purposes of this System. As recognized by the Office of Management and Budget (OMB) in its Privacy Act Implementation Guidance and Responsibilities (65 FR 19746 (July 9, 1975)), the routine uses include proper and necessary uses of information in the system, even if such uses occur infrequently. MARAD is including in this notice routine uses for disclosures to law enforcement when the record, on its face, indicates a violation of law, to DOJ for litigation purposes, or when necessary in investigating or responding to a breach of this system or other agencies' systems. MARAD may disclose to Federal, State, local, or foreign agency information relevant to law enforcement, litigation, and proceedings before any court or adjudicative or administrative body. OMB has long recognized that these types of routine uses are ''proper and necessary'' uses of information and qualify as compatible with agency systems (65 FR 19476, April 11, 2000). In addition, OMB Memorandum M–17–12, directed agencies to include routine uses that will permit sharing of information when needed to investigate, respond to, and mitigate a breach of a Federal information system. MARAD has also included routine uses that permit sharing with the National Archives and Records Administration when necessary for an inspection, to any Federal government agency engaged in audit or oversight related to this system. MARAD also has included routine uses that permit the sharing of information necessary for transferring USMMA students either to other schools or to the military, as it relates to requests under the Family Education Rights and Privacy Act (FERPA), as well as when in connection to the hiring, firing, or retention of an employee or contractor, or the issuance of a security clearance, license, certification, contract, grant, or other benefit. These types of disclosures are necessary and proper uses of information in this system because they further MARAD's obligation to fulfil its records management and program management responsibilities by facilitating accountability to agencies charged with oversight in these areas.

Public Participation

How do I submit comments on the proposed rule?

Your comments must be written and in English. Include the docket number in your comments to ensure that your comments are correctly filed in the Docket. We encourage you to provide concise comments; however, you may attach additional documents as necessary. There is no limit on the length of the attachments. Please submit your comments, including the attachments, following the instructions provided under the above entitled heading **ADDRESSES**.

MARAD will consider all comments received before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, MARAD will also consider comments received after that date.

For access to the docket to submit or read comments received, go to the Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590. The Docket Management Facility is open 9:00 a.m. to 5:00 p.m., Monday through Friday, except on Federal holidays. To review documents, read comments or to submit comments, the docket is also available online at *www.regulations.gov.,* keyword search ''MARAD–2021–0269.''

Will my comments be made available to the public?

Before including your address, phone number, email address or other personal information in your comment, be aware that your entire comment, including your personal identifying information, will be made publicly available. Anyone is able to search the electronic form of all comments received in 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.).

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. When you submit comments containing information claimed to be confidential information, you should include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

The Privacy Act (5 U.S.C. 552a) governs the means by which the federal government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any 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. The Privacy Act extends rights and protections to individuals who are U.S. citizens and lawful permanent residents. Additionally, the Judicial Redress Act (JRA) provides a covered person with a statutory right to make requests for access and amendment to covered records, as defined by the JRA, along with judicial review for denials of such requests. In addition, the JRA prohibits disclosures of covered records, except as otherwise permitted by the Privacy Act. You may review the DOT's complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *https://DocketsInfo.dot.gov.*

Below is the description of the USMMA Student Religious Accommodations Files System of Records. In accordance with 5 U.S.C. 552a(r), MARAD has provided a report of this system of records to the OMB and to Congress.

SYSTEM NAME AND NUMBER:

DOT/MARAD 035; USMMA Student Religious Accommodations Files

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are maintained by the United States Merchant Marine Academy (USMMA), 300 Steamboat Road, Kings Point, NY 11024, and other MARAD or Department of Transportation installations or offices.

SYSTEM MANAGER(S):

Commandant of Midshipmen, 300 Steamboat Road, Kings Point, New York 11024, *Commandantoffice@usmma.edu,* (516) 726–5664.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

- Executive Order 13160 of June 23, 2000—Nondiscrimination on the Basis of Race, Sex, Color, National Origin, Disability, Religion, Age, Sexual Orientation, and Status as a Parent in Federally Conducted Education and Training Programs.
- The Religious Freedom Restoration Act of 1993, Public Law 103–141.

PURPOSE(S) OF THE SYSTEM:

The purpose of the system is to collect information from USMMA students and accepted applicants seeking religious accommodations in order to approve or deny requests for religious accommodation.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who are USMMA students or accepted applicants who have requested religious accommodation.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records include names of individuals seeking accommodation, the nature of the request for accommodation, how complying with the relevant requirement would burden religious exercise, how long the belief asserted to be contrary to a MARAD or USMMA requirement has been held, and any other information necessary or helpful for USMMA to evaluate the request for accommodation. Personally identifiable information (PII) elements: Name, birth date, student photographic identification, residential address, phone number, email, USMMA campus address, other information submitted by requestors that they believe may be helpful in making a determination.

RECORD SOURCE CATEGORIES:

USMMA students and accepted applicants seeking religious accommodations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

System Specific Routine Uses

1. To all authorized recipients, such as a parent, medical facility, service provider, school, or branch of military to which the student is transferring, consistent with disclosures permitted or required by the Family Education Rights and Privacy Act (FERPA), or required by another Federal statute.

General Routine Uses

The following routine uses may be subject to restrictions on disclosure by another law, including but not limited to FERPA:

1. To Federal, State, territorial, local, tribal, or foreign agencies that have requested information relevant or necessary to the hiring, firing, or retention of an employee or contractor, or the issuance of a security clearance, license, certification, contract, grant, or other benefit, when the disclosure is compatible with the purpose for which the records were compiled.

2. In the event that a system of records maintained by MARAD/USMMA to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether Federal, State, local or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation, or order.

3. Routine Use for Disclosure for Use in Litigation.

(a) It will be a routine use of the records in this system of records to disclose them to the Department of Justice or other Federal agency conducting litigation when—(i) MARAD or USMMA, or (ii) Any employee of MARAD/USMMA, in their official capacity, or (iii) Any employee of MARAD/USMMA, in their individual capacity where the Department of Justice has agreed to represent the employee, or (iv) The United States or any agency thereof, where MARAD determines that litigation is likely to affect the United States, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice or other Federal agency conducting the litigation is deemed by MARAD to be relevant and necessary in the litigation.

(b) Routine Use for Agency Disclosure in Other Proceedings. It will be a routine use of records in this system to disclose them in proceedings before any court or adjudicative or administrative body before which MARAD/USMMA, appears, when—(a) MARAD/USMMA, or (b) Any employee of MARAD/USMMA in their official capacity, or (c) Any employee of MARAD/USMMA in their individual capacity where MARAD has agreed to represent the employee, or (d) The United States or any agency thereof, where MARAD determines that the proceeding is likely to affect the United States, is a party to the proceeding or has an interest in such proceeding, and MARAD determines that use of such records is relevant and necessary in the proceeding.

4. Disclosure may be made to a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual. In such cases, however, the Congressional office does not have greater rights to records than the individual. Thus, the disclosure may be withheld from delivery to the individual where the file contains investigative or actual information or other materials which are being used, or are expected to be used, to support prosecution or fines against the individual for violations of a statute, or of regulations of the Department based on statutory authority. No such limitations apply to records requested for Congressional oversight or legislative purposes; release is authorized under 49 CFR 10.35(9).

5. One or more records from a system of records may be disclosed routinely to the National Archives and Records Administration (NARA) in records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

6. DOT may disclose records from the system, as a routine use to appropriate agencies, entities, and persons when (1) DOT suspects or has confirmed that there has been a breach of the system of records, (2) DOT has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DOT (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 DOT's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

7. DOT may disclose records from the system, as a routine use to another Federal agency or Federal entity, when DOT 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.

8. MARAD may disclose records from this system, as a routine use, to the Office of Government Information Services for the purpose of (i) resolving disputes between FOIA requesters and federal agencies and (ii) reviewing agencies' policies, procedures, and compliance in order to recommend policy changes to Congress and the President.

9. MARAD may disclose records from the system, as a routine use, to contractors and their agents, experts, consultants, and others performing or working on a contract, service, cooperative agreement, or other assignment for MARAD, when necessary to accomplish an agency function related to this system of records.

10. MARAD may disclose records from this system, as a routine use, to an agency, organization, or individual for the purpose of performing audit or oversight operations related to this system of records, but only such records as are necessary and relevant to the audit or oversight activity. This routine use does not apply to intra-agency sharing authorized under Section (b)(1) of the Privacy Act and FERPA.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records in this system are stored in paper/hard copy at a federally controlled installation. Department of Transportation (DOT) Operating Administrations safeguard records in all system of records according to applicable rules, policies, and procedures, including all applicable DOT automated systems security and access policies. DOT 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. DOT routinely employs safeguards such as the following to information systems and paper recordkeeping systems: Multifactor log-in authentication and password; 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 and detection.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records on individuals will be retrieved by name.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records will be held in accordance with Records Control Schedule, RG–0357 Maritime Administration, Comprehensive Schedule, Sections 855 and 864. Individual files created, received, and maintained for the purpose of providing reasonable accommodations that have been requested for or by a USMMA student or accepted applicant, including the following: Requests, approvals, and denials, notice of procedures for informal dispute resolution or appeal processes, forms, correspondence, records of oral conversations, policy guidance documents, supporting notes and documentation. Accordingly, the records will be destroyed 60 years after the information provider's departure or graduation from the USMMA.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DOT/MARAD/USMMA security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RECORD ACCESS PROCEDURES:

When seeking records about yourself from this system of records or any other MARAD/USMMA system of records, your request must conform with the Privacy Act regulations set forth in 49 CFR part 10. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. Individual USMMA accepted applicants or students seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request, in accordance with FERPA, in writing to the System Manager at the address identified in ''System Manager and Address'' above. Individuals may also search the public docket at *www.regulations.gov* by their name.

You may also request information under the FOIA. While no specific form is required, you should provide to MARAD's FOIA Officer (contact information available on MARAD's website) the following information:

- An explanation of why you believe the MARAD/USMMA would have information about you;
- Identify which component(s) of MARAD/USMMA you believe may have the information about you;
- Specify when you believe the records would have been created;
- Provide any other information that will help the FOIA staff determine which MARAD/USMMA component may have responsive records; and

If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying their agreement for you to access their records. Without this bulleted information the component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures.

NOTIFICATION PROCEDURES:

See Record Access Procedures.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

* * * * *

By Order of the Acting Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2021–28077 Filed 12–23–21; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF VETERANS AFFAIRS

Reimbursement for Caskets and Urns for Burial of Unclaimed Remains in a National Cemetery or a VA-Funded State or Tribal Veterans' Cemetery

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA) is updating the monetary reimbursement rates for caskets and urns purchased for interment in a VA national cemetery or a VA-funded state or tribal veterans' cemetery of veterans who die with no known next of kin and where there are insufficient resources for furnishing a burial container. The purpose of this notice is to notify interested parties of the rates that will apply to reimbursement claims that occur during calendar year (CY) 2022.

DATES: This notice is effective January 1, 2022.

FOR FURTHER INFORMATION CONTACT: Jerry Sowders, National Cemetery Administration, Department of Veterans Affairs, 4850 Lemay Ferry Road, Saint Louis, MO, 63129. The telephone number is 314–416–6369. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Section 2306(f) of title 38, United States Code, authorizes VA's National Cemetery Administration to furnish a casket or urn for interment in a VA national cemetery or a VA-funded state or tribal veterans' cemetery of the unclaimed remains of veterans for whom VA cannot identify a next of kin, and determines that sufficient financial resources for the furnishing of a casket or urn for burial are not available. VA established regulations to administer this authority as a reimbursement benefit in 38 CFR 38.628.

In accordance with the regulation, reimbursement for a claim received in any CY will not exceed the average cost of a 20-gauge metal casket or a durable plastic urn during the fiscal year (FY) preceding the CY of the claim, as determined by VA.

Average costs are based on market price analysis and previous year actual reimbursements for 20-gauge metal caskets, designed to contain human remains, with a gasketed seal, and external rails or handles. The same analysis is completed for durable plastic urns, designed to contain human remains, which include a secure closure to contain the cremated remains.

Using this approach, in FY 2021, the average costs were determined to be $1,362.00 for caskets and $120.00 for urns. Accordingly, the maximum reimbursement rates payable for qualifying interments occurring during CY 2022 are $1,362.00 for caskets and $120.00 for urns.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on December 20, 2021, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Luvenia Potts,

Regulation Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

[FR Doc. 2021–27947 Filed 12–23–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0629]

Agency Information Collection Activity: Application for Extended Care Services

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Health Administration (VHA), 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 extension 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 February 25, 2022.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Janel Keyes, Office of Regulations, Appeals, and Policy (10BRAP), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *Janel.Keyes@va.gov.* Please refer to ''OMB Control No. 2900–0629'' 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), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0629'' 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, VHA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA'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: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: Application for Extended Care Services, VA Form 10–10EC.

OMB Control Number: 2900–0629.

Type of Review: Reinstatement of a previously approved collection.

Abstract: Title 38 U.S.C. Chapter 17 authorizes VA to provide hospital care, medical services, domiciliary care, and nursing home care to eligible Veterans. Title 38 U.S.C. 1705 requires VA to design, establish and operate a system of annual patient enrollment in accordance with a series of stipulated priorities. A consequence of this is that many groups of Veterans who are in a lower priority group (WWI Veterans, Veterans with disabilities rated as 0% service-connected seeking treatment for other than their service-connected conditions, Veterans exposed to a toxic substance, radiation, or environmental hazard and nonservice-connected Veterans) may request that they be allowed to be income tested in order to gain a higher priority. Title 38 U.S.C. 1722 establishes eligibility assessment procedures for cost-free VA medical care, based on income levels, which will determine whether nonservice-connected and 0% service-connected non-compensable Veterans are able to defray the necessary expenses of care for nonservice-connected conditions. Title 38 U.S.C. 1722A establishes the eligibility assessment procedures, based on income levels, for determining Veterans' eligibility for cost-free medications and Title 38 U.S.C. 1710B defines the procedures for establishing eligibility for cost-free Extended Care benefits. Title 38 U.S.C § 1729 authorizes VA to recover from Veterans' health insurance carriers the cost of care furnished for their nonservice-connected conditions.

VA Form 10–10EC, Application for Extended Care Services, is used to collect financial information necessary to determine a Veteran's copayment obligation for extended care services, also known as long term care (LTC).

Affected Public: Individuals or households.

Estimated Annual Burden: 3,000 hours.

Estimated Average Burden per Respondent: 90 minutes.

Frequency of Response: Once annually.

Estimated Number of Respondents: 2,000.

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. 2021–27918 Filed 12–23–21; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 86 Monday,

No. 245 December 27, 2021

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412 and 413

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; Changes to Medicare Graduate Medical Education Payments for Teaching Hospitals; Changes to Organ Acquisition Payment Policies; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412 and 413

[CMS–1752–FC3]

RIN 0938–AU44

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; Changes to Medicare Graduate Medical Education Payments for Teaching Hospitals; Changes to Organ Acquisition Payment Policies

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period finalizes certain provisions of the fiscal year 2022 IPPS/LTCH PPS proposed rule. These provisions implement policies based on legislative changes relative to Medicare graduate medical education (GME) for teaching hospitals provided by sections 126, 127, and 131 of the Consolidated Appropriations Act (CAA), 2021; and changes, clarifications, and codifications for Medicare organ acquisition payment policies relative to organ procurement organizations (OPOs), transplant hospitals, and donor community hospitals. In addition, this final rule with comment period solicits comments on certain GME issues to inform potential future rulemaking

DATES:

Effective date: This final rule with comment period is effective February 25, 2022.

Comment date: To be assured consideration, comments on the graduate medical education provisions discussed in sections II.B.3.b.(5), II.B.3.d.(2). and II.B.5.e. of this final rule with comment period must be received at one of the addresses provided below, by February 25, 2022.

ADDRESSES: In commenting, please refer to file code CMS–1752–FC3.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1752–FC3, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1752–FC3, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Donald Thompson, (410) 786–4487, and Michele Hudson, (410) 786–4487, Graduate Medical Education Issues.

Katie Lucas, (410) 786–7723, Amanda Michael, (410) 786–5834, and Kellie Shannon (410) 786–0416, Organ Acquisition Payment Issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

Under various statutory authorities, we either discuss continued program implementation or are making changes to the Medicare IPPS, other related payment methodologies and programs and other policies and provisions included in this rule. The purpose of and the statutory authority(ies) for these changes include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates, including indirect medical education (IME) payments under section 1886(d)(5)(B) of the Act.
- The Consolidated Appropriations Act of 2021 relating to payments to hospitals for direct graduate medical education (GME) and indirect medical education (IME) costs. Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act.
- Organ acquisition costs are reimbursed to transplant hospitals and kidney acquisition costs are reimbursed to organ procurement organizations under reasonable cost principles under section 1861(v) of the Act. Under 42 U.S.C. 273(b), organ procurement organizations must have an agreement with the Secretary to be reimbursed under title XVIII of the Social Security Act for the cost to procure kidneys.

2. Summary of the Provisions

The following is a summary of the provisions in this final rule with comment period.

a. Implementation of Sections 126, 127, and 131 of the Consolidated Appropriations Act (CAA) of 2021

We are finalizing provisions to implement sections 126, 127, and 131 of the CAA. Section 126(a) of the CAA amended section 1886(h) of the Act by adding a new section 1886(h)(9) of the Act requiring the distribution of additional residency positions to qualifying hospitals. Section 127 of the CAA amended section 1886(h)(4)(H)(iv) of the Act to specify that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural track) in a rural area, the hospital, and each such hospital located in a rural area that participates in such a training, is allowed to receive an adjustment to its full-time equivalent (FTE) resident limit. Section 131 of the CAA amended section 1886(h)(2)(F) of the Act to provide an opportunity to hospitals with such extremely low or $0 per resident amounts (PRAs) that meet certain criteria to reset and establish new PRAs if the hospital trains resident(s) in a cost reporting period

beginning on or after enactment (December 27, 2020) and before the date that is 5 years after enactment (December 26, 2025). Section 131 of the CAA also amended section 1886(h)(4)(H)(i) of the Act to provide an opportunity for hospitals that meet certain criteria and that have very small FTE resident caps to replace those caps if the Secretary determines the hospital begins training residents in a new program beginning on or after enactment (December 27, 2020) and before 5 years after enactment (December 26, 2025).

In addition, this final rule with comment period solicits comments on certain issues to inform potential future rulemaking. Specifically, for the implementation of section 126 of the CAA regarding distribution of residency slots, we seek comment on using a measure of health care provided outside of a Health Professional Shortage Area (HPSA) to HPSA residents (as discussed in section II.B.3.b.(5) of the preamble of this final rule with comment period). For purposes of prioritizing hospitals awarded residency positions under section 126, we seek comment on feasible alternatives to HPSA scores as a proxy for health disparities (as discussed in section II.B.3.d.(2) of the preamble of this final rule). In addition, for the implementation of section 131, we seek comment on the review process to determine eligibility for per resident amount or full-time equivalent cap resets in situations where a hospital disagrees with the information on the cost report, in particular from cost reports that are no longer within the 3-year reopening period (as discussed in section II.B.5.e. of the preamble of this final rule).

We refer readers to section II.B.2. of this final rule with comment period for a summary of the provisions of sections 126, 127, and 131 of the CAA that we are implementing in this final rule with comment period.

b. Changes to Organ Acquisition Payment Policy

We proposed changes pertaining to Medicare's share of organ acquisition costs transplanted into Medicare beneficiaries. We also proposed changes to longstanding Medicare organ acquisition payment policies and changes pertaining to charges for services provided to cadaveric organ donors by donor community hospitals. After considering the numerous public comments received, at this time, we are not finalizing our proposal with respect to the organ counting policy for Medicare's organ acquisition payment purposes and the research organ counting policy. We are finalizing other longstanding Medicare organ acquisition payment policies with some modifications. We are also finalizing rules with respect to Medicare-certified non-transplant hospitals and transplant hospitals' charges for hospital services provided to cadaveric donors, effective for cost reporting periods beginning on or after the effective date of this final rule with comment period.

3. Summary of Costs, Savings, Benefits, and Transfers

The following table provides a summary of the costs, savings, benefits associated with the provisions described in section I.A.2. of this final rule.

Provision description	Description of costs, transfers, savings, and benefits
Implementation of Sections 126, 127, and 131 of the Consolidated Appropriations Act (CAA) of 2021.	Section 1886(h) of the Act, as amended by sections 126, 127, and 131 of the CAA, provides for the distribution of additional residency positions (section 126), promotes a rural hospital GME funding opportunity (section 127), and requires resetting PRAs and FTE resident caps for certain hospitals after hosting medical resident rotators for short durations (section 131). We refer readers to section II.B. of this final rule with comment period for a summary of the provisions of sections 126, 127 and 131 that we are implementing in this final rule. We estimate that our implementation of section 126 of the CAA will result in an estimated cost of approximately $1.830 billion from FY 2023 through FY 2031. We estimate that our implementation of section 127 of the CAA will result in an estimated cost of approximately $0.130 billion from FY 2024 through FY 2031. We estimate our implementation of section 131 of the CAA will result in an estimated cost of approximately $1.380 billion from FY 2022 through FY 2031.
Changes to Organ Acquisition Payment Policy	We refer readers to sections II.C.2.a. through g. and i through m. and II.C.3. of this final rule with comment period for a summary of organ acquisition payment policies we are implementing in this final rule. These final policies are not expected to have an impact on expenditures. However, the provisions in sections II.C.2.b., e. and l. of this final rule with comment period to the extent that any of these provisions may have an impact on expenditures, that impact is not estimable without the availability of the appropriate cost information to calculate such impact.

B. Background

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Act sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these ''subsection (d) hospitals.'' Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital is training residents in an approved residency program(s), it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M. The existing regulations governing the IME adjustment are located in § 412.105.

2. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing direct GME payments to the various types of hospitals are located in 42 CFR part 413.

3. Issuance of Proposed Rulemaking

In the FY 2022 IPPS/LTCH PPS proposed rule appearing in the May 10, 2021 **Federal Register** (86 FR 25070), we set forth proposed payment and policy changes to the Medicare IPPS for FY 2022 operating costs and capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS. In addition, we set forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with payment rate policies under the LTCH PPS for FY 2022.

The following is a general summary of the changes that we proposed to make related to the provisions addressed in this final rule with comment period.

In section V. of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we discussed proposed changes to certain provisions of the regulations in 42 CFR parts 412 and 413, including proposals to implement provisions of the Consolidated Appropriations Act relating to payments to hospitals for direct graduate medical education (GME) and indirect medical education (IME) costs.

Section X. of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule included proposed changes pertaining to Medicare's share of organ acquisition costs for organs transplanted into Medicare beneficiaries and the charges for services provided to cadaveric organ donors by donor community hospitals and transplants hospitals.

In Appendix A of the FY 2022 IPPS/LTCH PPS proposed rule, we set forth an analysis of the impact the proposed changes for the provisions listed would have on affected acute care hospitals, IPPS-excluded hospitals and other entities.

We received approximately 28,000 timely pieces of correspondence in response to the FY 2022 IPPS/LTCH PPS proposed rule. Approximately 570 items of the proposed rule's correspondence are addressed in this final rule with comment period.

We also note that the FY 2022 IPPS/LTCH PPS final rule appeared in the August 13, 2021 **Federal Register** (86 FR 44774) and that final rule included the vast majority of the provisions of the proposed rule. This final rule with comment period finalizes the graduate medical education and certain organ acquisition payment policy provisions of the FY 2022 IPPS/LTCH PPS proposed rule. As noted in section II.A. of this final rule with comment period, we are not addressing the proposed revisions to the regulations relating to the treatment of section 1115 waiver days for purposes of the disproportionate share hospital (DSH) adjustment in this final rule with comment period. We expect to revisit the issue of section 1115 waiver days in future rulemaking, and we encourage stakeholders to review any future proposal on this issue and to submit their comments at that time. As noted in section II.C. of this final rule with comment period, we are not addressing the proposed revisions to the Medicare organ counting policy in this final rule with comment period. We may revisit the Medicare organ counting policy in future rulemaking, and we encourage stakeholders to review any future proposal on this issue and to submit their comments at that time.

II. Provisions of the Final Rule With Comment Period

A. Medicare Disproportionate Share Hospital (DSH) Payments: Counting Days Associated With Section 1115 Demonstration Projects in the Medicaid Fraction (§ 412.106)

In the FY 2022 IPPS/LTCH PPS proposed rule, we proposed revisions to the regulation relating to the treatment of section 1115 waiver days for purposes of the DSH adjustment (86 FR 25457 through 25459). In the FY 2022 IPPS/LTCH PPS final rule, we stated that due to the number and nature of the comments that we received on our proposal, we intended to address the public comments in a separate document (86 FR 45249). We thank the commenters for their input on the proposal, but after further consideration of the issue, we have determined not to move forward with the current proposal. We expect to revisit the issue of section 1115 waiver days in future rulemaking, and we encourage stakeholders to review any future proposal on this issue and to submit their comments at that time.

B. Payment for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 Through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) and as currently implemented in the regulations at 42 CFR 413.75 through 413.83, establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for determining a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). The base year PRA is updated annually for inflation. In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days.

Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the IPPS for hospitals that have residents in an approved GME program, in order to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment are located at 42 CFR 412.105. The hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital to the number of inpatient hospital beds.

The calculation of both direct GME payments and the IME payment adjustment is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress, through the Balanced Budget Act of 1997 (Pub. L.

105–33), established a limit on the number of allopathic and osteopathic residents that a hospital could include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied, effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

Section 422 of Public Law 108–173, the Medicare Modernization Act (MMA), provided for the redistribution of unused residency positions effective for portions of cost reporting periods beginning on or after July 1, 2005. The policy implementing section 422 of the MMA was included in the August 11, 2004 FY 2005 IPPS final rule (69 FR 49112 through 49169).

The Affordable Care Act made a number of statutory changes relating to the determination of a hospital's FTE resident limit for direct GME and IME payment purposes and the manner in which FTE resident limits are calculated and applied to hospitals under certain circumstances.

Section 5503(a)(4) of the Affordable Care Act added a new section 1886(h)(8) to the Act to provide for the reduction in FTE resident caps for direct GME under Medicare for certain hospitals training fewer residents than their caps, and to authorize the redistribution of the estimated number of excess FTE resident slots to other qualified hospitals. In addition, section 5503(b) of the Affordable Care Act amended section 1886(d)(5)(B)(v) of the Act to require the application of the section 1886(h)(8) of the Act provisions in the same manner to the IME FTE resident caps. The policy implementing section 5503 of the Affordable Care Act was included in the November 24, 2010 CY 2011 OPPS/ASC final rule with comment period (75 FR 72147 through 72212) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53424 through 53434). Section 5506(a) of the Affordable Care Act amended section 1886(h)(4)(H) of the Act to add a new clause (vi) that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria up to the number of the closed hospital's FTE resident caps. The policy implementing section 5506 of the Affordable Care Act was included in the November 24, 2010 CY 2011 OPPS/ASC final rule with comment period (75 FR 72212 through 72238), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434 through 53448), and the FY 2015 IPPS/LTCH final rule (79 FR 50122 through 50140).

2. Provisions of the Consolidated Appropriations Act, 2021

The Consolidated Appropriations Act, 2021 (CAA), division CC, contained 3 provisions affecting Medicare direct GME and IME payments to teaching hospitals. Section 126 of the CAA makes available 1,000 new Medicare-funded GME positions (but not more than 200 new positions for a fiscal year), to be distributed beginning in fiscal year 2023, with priority given to hospitals in 4 statutorily-specified categories. Section 127 of the CAA makes statutory changes relating to the determination of both an urban and rural hospital's FTE resident limit for direct GME and IME payment purposes with regard to residents training in an accredited rural training track (RTT), and the 3-year rolling average set out at section 1886(h)(4)(G)(i) of the Act used to calculate payments for these hospitals. Section 131 of the CAA makes statutory changes to the determination of direct GME PRAs and direct GME and IME FTE resident limits of hospitals that hosted a small number of residents for a short duration. We provided detailed proposals for implementing these three CAA provisions in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25502 through 25523). In this section of this final rule with comment period, we discuss our proposals, respond to public comments received, and provide our final policies.

3. Distribution of Additional Residency Positions Under the Provisions of Section 126 of Division CC of the Consolidated Appropriations Act, 2021 (CAA)

a. Overview

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25503 through 25504), section 126(a) of the CAA amended section 1886(h) of the Act by adding a new section 1886(h)(9) of the Act requiring the distribution of additional residency positions to qualifying hospitals. Section 1886(h)(9)(A) of the Act requires that for FY 2023, and for each succeeding fiscal year until the aggregate number of full-time equivalent (FTE) residency positions distributed is equal to 1,000, the Secretary shall initiate separate rounds of applications from hospitals for these additional residency positions. The Secretary is required, subject to certain provisions in the law, to increase the otherwise applicable resident limit for each qualifying hospital that submits a timely application by the number of positions that may be approved by the Secretary for that hospital. The Secretary is required to notify hospitals of the number of positions distributed to them by January 31 of the fiscal year of the increase, and the increase is effective beginning July 1 of that fiscal year. Section 1886(h)(9)(A) of the Act also limits the aggregate number of such positions made available in a single fiscal year across all hospitals to no more than 200.

In determining the qualifying hospitals for which an increase is provided, section 1886(h)(9)(B) of the Act requires the Secretary to take into account the ''demonstrated likelihood'' of the hospital filling the positions made available within the first 5 training years beginning after the date the increase would be effective, as determined by the Secretary.

Section 1886(h)(9)(B) of the Act also requires a minimum distribution for certain categories of hospitals. Specifically, the Secretary is required to distribute at least 10 percent of the aggregate number of total residency positions available to each of four categories of hospitals. Stated briefly, and discussed in greater detail later in this final rule with comment period, the categories are as follows: (1) Hospitals located in rural areas or that are treated as being located in a rural area (pursuant to sections 1886(d)(2)(D) and 1886(d)(8)(E) of the Act); (2) hospitals in which the reference resident level of the hospital is greater than the otherwise applicable resident limit; (3) hospitals in states with new medical schools or additional locations and branches of existing medical schools; and (4) hospitals that serve areas designated as Health Professional Shortage Areas (HPSAs). Section 1886(h)(9)(F)(ii) of the Act defines a qualifying hospital as a hospital in one of these four categories.

Section 1886(h)(9)(C) of the Act places certain limitations on the distribution of the residency positions. First, a hospital may not receive more than 25 additional FTE residency positions in total. Second, no increase in the otherwise applicable resident limit of a hospital may be made unless the hospital agrees to increase the total number of FTE residency positions under the approved medical residency

training program of the hospital by the number of positions made available to that hospital.

b. Determinations Required for the Distribution of Residency Positions

(1) Determination That a Hospital Has a ''Demonstrated Likelihood'' of Filling the Positions

Section 1886(h)(9)(B)(i) of the Act directs the Secretary to take into account the ''demonstrated likelihood'' of the hospital filling the positions made available within the first 5 training years beginning after the date the increase would be effective, as determined by the Secretary.

Section 1886(h)(9)(A)(iii)(II) of the Act requires that the increase would be effective beginning July 1 of the fiscal year of the increase. For FY 2023, this means the additional positions would be effective July 1, 2023.

In the FY 2022 IPPS/LTCH PPS proposed rule, we proposed that the application deadline for the additional positions available for a fiscal year would be January 31 of the prior fiscal year. However, as discussed later in this final rule with comment period, we are finalizing a deadline of March 31, such that the application deadline for the additional positions available for a fiscal year will be March 31 of the prior fiscal year. Accordingly, for FY 2023, all references in section II.B.3. of this final rule with comment period to the application deadline are references to the application deadline of March 31, 2022.

We proposed that a hospital would show a ''demonstrated likelihood'' of filling the additional positions (sometimes equivalently referred to as slots) for which it applies by demonstrating that it does not have sufficient room under its current FTE resident cap(s) to accommodate a planned new program or expansion of an existing program.

In order to demonstrate that it does not have sufficient room under its current FTE resident cap(s), we proposed that a hospital would be required to submit copies of its most recently submitted Worksheets E, Part A and E–4 from the Medicare cost report (CMS–Form–2552–10) as part of its application for an increase to its FTE resident cap.

We proposed that a hospital would demonstrate and attest to a planned new program or expansion of an existing program by meeting at least one of the following two criteria:

• ''*Demonstrated Likelihood*'' *Criterion 1 (New Residency Program).* The hospital does not have sufficient room under its FTE resident cap, and the hospital intends to use the additional FTEs as part of a new residency program that it intends to establish on or after the date the increase would be effective (that is, a new program that begins training residents at any point within the hospital's first 5 training years beginning on or after the date the increase would be effective).

Under ''Demonstrated Likelihood'' Criterion 1, we proposed that the hospital would be required to meet at least one of the following conditions as part of its application:

☐ Application for approval of the new residency program has been submitted to the ACGME or the American Board of Medical Specialties (ABMS) by the application deadline for that year.

☐ The hospital has submitted an institutional review document or program information form concerning the new residency program in an application for approval of the new program by the application deadline for that year.

☐ The hospital has received written correspondence by the application deadline for that year from the ACGME or ABMS acknowledging receipt of the application for the new residency program, or other types of communication from the accrediting bodies concerning the new program approval process (such as notification of site visit).

• ''*Demonstrated Likelihood*'' *Criterion 2 (Expansion of an Existing Residency Program).* The hospital does not have sufficient room under its FTE resident cap, and the hospital intends to use the additional FTEs to expand an existing residency training program within the hospital's first 5 training years beginning on or after the date the increase would be effective. Under ''Demonstrated Likelihood'' Criterion 2, we proposed that the hospital would be required to meet at least one of the following conditions as part of its application:

☐ The hospital has approval by the application deadline from an appropriate accrediting body (the ACGME or ABMS) to expand the number of FTE residents in the program.

☐ The hospital has submitted by the application deadline an institutional review document or program information form for the expansion of the existing residency training program.

Under ''Demonstrated Likelihood'' Criterion 2, we proposed that the hospital would be applying for an increase in its FTE resident cap in order to expand an existing residency program. We proposed that this would mean that as of the application deadline the hospital was either already training residents in this program, or, if the program existed at another hospital as of that date, the residents would begin to rotate at the applying hospital on or after the effective date of the increase.

We note that section 1886(h)(9)(C)(ii) of the Act requires that if a hospital is awarded positions, that hospital must increase the number of its residency positions by the amount the hospital's FTE resident caps are increased based on the newly awarded positions under section 126 of CAA. We therefore proposed that a hospital must, as part of its application, attest to increase the number of its residency positions by the amount the hospital's FTE resident caps are increased based on any newly awarded positions.

We present a summary of the public comments and our responses to our proposals related to the determination that a hospital has a ''demonstrated likelihood'' of filling the positions awarded under section 126 of the CAA.

Comment: Several commenters expressed support for our proposed ''Demonstrated Likelihood'' criteria.

Response: We thank the commenters for their support.

Comment: A commenter supported our proposal to award additional residency positions only for newly-created positions, rather than for existing positions that a hospital may already be funding in excess of its statutory FTE caps. Conversely, another commenter expressed concern that hospitals training residents over their caps are neglected by our proposed ''Demonstrated Likelihood'' criteria. This commenter questioned why such hospitals were not being prioritized in the distribution of additional residency positions, given the commenter's belief that there is almost certain likelihood that additional residency positions awarded to these hospitals would be immediately filled and utilized.

Response: Section 1886(h)(9)(C)(ii) of the Act, as added by section 126 of the CAA, prohibits an increase in the otherwise applicable resident limit of a hospital unless the hospital agrees to increase its total number of FTE residency positions. Our proposed ''Demonstrated Likelihood'' criteria thus reflect the requirements set forth in the statute, which preclude the use of additional residency positions to fund existing positions. In response to the comment that hospitals that do not have sufficient room under their current FTE resident cap(s) (that is, hospitals that are training at or above their Medicare GME cap(s) and do not have any remaining

Medicare funding for positions to train additional FTE residents) should be prioritized in the distribution of additional residency positions, we note, as discussed in this section, that HPSA scores, while not a perfect measure, provide the best prioritization approach available at this time. In addition, and as discussed later in this section, in order to be eligible for prioritization based on HPSA scores, hospitals must first qualify under one or more of Category One, Category Two, Category Three, or Category Four. Category Two consists of hospitals in which the reference resident level of the hospital is greater than the otherwise applicable resident limit. Therefore, hospitals that do not have sufficient room under their current FTE resident caps, may qualify to be prioritized for the distribution of additional residency positions based on our prioritization of applications from hospitals based on HPSA score final policy, discussed further in this section.

Comment: A commenter suggested that hospitals should be able to meet the ''demonstrated likelihood'' requirement by showing that the number of residency positions currently filled for one or more programs at the hospital is less than the number of residents for which those programs have been accredited by the ACGME. Another commenter made a similar point by requesting that the number of residency positions distributed to a hospital take into account the hospital's ability to use those residency positions immediately through existing programs. Another commenter stated that the reason a hospital has unfilled accredited residency positions may be that the hospital would be unable to train the full complement of residents without exceeding its FTE caps; the commenter added that such hospitals would not actually need to establish a new residency program or expand an existing program in order to quickly put any additional residency positions awarded to them to use.

Response: We agree that a hospital should be able to meet the ''demonstrated likelihood'' requirement by showing that it has unfilled, previously accredited positions in its residency program, and that it is now seeking to fill those positions, as long as the hospital does not have sufficient room under its FTE resident cap(s) for the planned expansion. Therefore, we are modifying ''Demonstrated Likelihood'' Criterion 2 (Expansion of an Existing Residency Program) to include the scenario where a hospital currently has unfilled positions in its residency program that have previously been approved by the ACGME and is now seeking to fill those positions.

Comment: Several commenters recommended that rural hospitals should only be awarded additional residency positions for the purpose of expanding existing programs, since such hospitals can already receive a cap adjustment whenever they establish a new program.

Response: We believe rural hospitals should be given the option of receiving a permanent cap increase for a new program either under section 126 of the CAA, or under the existing 5-year cap-building process (42 CFR 413.70(e)). A rural hospital making this decision should carefully consider which option is more appropriate to its specific scenario.

Comment: A commenter expressed concern that many small rural hospitals would be unlikely to meet the proposed requirements for residency positions under ''Demonstrated Likelihood'' Criterion 2 (Expansion of an Existing Residency Program), since such hospitals often restrict the size of their programs for reasons other than funding, for example, because of teaching capacity or recruiting challenges. The commenter stated that only large rural hospitals with established programs would be likely to meet the proposed requirements under ''Demonstrated Likelihood'' Criterion 2.

Response: We appreciate the concerns raised by the commenter about unique challenges that may be faced by small rural hospitals. However, the statute requires us to take into account the ''demonstrated likelihood'' of a hospital filling the positions. Expansion of an existing program is a valid way for a hospital to demonstrate the likelihood of filling the positions. We note that since we are adopting a criterion that 50 percent of the program's training take place in the HPSA and not at the applicant hospital as proposed (which is discussed in section II.B.3.d. of this final rule with comment period), a rural hospital may be able to more easily partner with other participating training sites to meet the 50 percent criterion and be able to apply (and meet the requirements for ''demonstrated likelihood'') for the amount of FTEs that will be training at its (the rural) hospital.

Comment: Several commenters requested that we update our proposed ''Demonstrated Likelihood'' criteria to be consistent with the terminology currently used by the ACGME and the ABMS. Specifically, commenters noted that the ACGME ''accredits'' new residency programs, whereas we used the term ''approval'' in our proposed criteria. In addition, the ACGME no longer employs the terms ''institutional review document'' or ''program information form.'' Rather, if an existing ACGME-accredited program seeks to expand, the program director would submit a request to the relevant specialty Review Committee for a permanent complement increase. Finally, commenters noted that ACGME accreditation deadlines occur multiple times per year, whereas in our proposal we referred to requirements that must be satisfied ''by the application deadline for that year''.

Response: We thank commenters for bringing the terminology issues to our attention and are revising the language accordingly as summarized below. However, we believe that the commenters have misinterpreted our references to the ''application deadline'' as references to the ACGME accreditation deadlines. In the context of our proposed ''Demonstrated Likelihood'' criteria, the ''application deadline'' refers to the deadline for submitting applications to CMS for additional residency positions under section 126 of the CAA, not the deadline for submitting program materials to the ACGME or the ABMS, as the commenters stated. We are therefore also clarifying that the phrase ''application deadline'' used in this context refers to the deadline for submitting applications under section 126 of the CAA for a given fiscal year. (As noted previously, in this final rule with comment period we are revising this deadline to March 31 of the prior fiscal year.)

In summary, after consideration of the public comments received, we are finalizing our proposed policy regarding the determination that a hospital has demonstrated a likelihood of filling the positions for ''Demonstrated Likelihood'' Criterion 1 (New Residency Program) with modifications. Under the policy finalized in this final rule with comment period, as we proposed, a hospital will show a ''demonstrated likelihood'' of filling the additional positions (sometimes equivalently referred to as slots) for which it applies by demonstrating that it does not have sufficient room under its current FTE resident cap(s) to accommodate a planned new program or expansion of an existing program. To do so, as we proposed, we are finalizing a policy that a hospital will submit copies of its most recently submitted Worksheets E, Part A and E–4 from the Medicare cost report (CMS–Form–2552–10) as part of its application for an increase to its FTE resident cap, and will demonstrate and attest to a planned new program or

expansion of an existing program by meeting at least one of two ''Demonstrated Likelihood'' criteria.

Specifically, we are finalizing the following for ''Demonstrated Likelihood'' Criterion 1:

• ''*Demonstrated Likelihood*'' *Criterion 1 (New Residency Program).* The hospital does not have sufficient room under its FTE resident cap, and the hospital intends to use the additional FTEs as part of a new residency program that it intends to establish on or after the date the increase would be effective (that is, a new program that begins training residents at any point within the hospital's first 5 training years beginning on or after the date the increase would be effective). Under ''Demonstrated Likelihood'' Criterion 1, the hospital will be required to meet at least one of the following conditions as part of its application:

□ Application for accreditation of the new residency program has been submitted to the ACGME (or application for approval of the new residency program has been submitted to the ABMS) by the application deadline.

□ The hospital has received written correspondence from the ACGME (or ABMS) acknowledging receipt of the application for the new residency program, or other types of communication concerning the new program accreditation or approval process (such as notification of site visit) by the application deadline.

For ''Demonstrated Likelihood'' Criterion 2, we are finalizing the following:

• ''*Demonstrated Likelihood*'' *Criterion 2 (Expansion of an Existing Residency Program).* The hospital does not have sufficient room under its FTE resident cap, and the hospital intends to use the additional FTEs to expand an existing residency training program within the hospital's first 5 training years beginning on or after the date the increase would be effective. Under ''Demonstrated Likelihood'' criterion 2, the hospital will be required to meet at least one of the following conditions as part of its application:

□ The hospital has received approval by the application deadline from an appropriate accrediting body (the ACGME or ABMS) to expand the number of FTE residents in the program.

□ The hospital has submitted a request by the application deadline for a permanent complement increase of the existing residency program.

□ The hospital currently has unfilled positions in its residency program that have previously been approved by the ACGME and is now seeking to fill those positions.

We are also finalizing, as we proposed, a policy that under ''Demonstrated Likelihood'' Criterion 2, the hospital is applying for an increase in its FTE resident cap because it is expanding an existing residency program. This means that as of the application deadline the hospital is either already training residents in this program, or, if the program exists at another hospital as of that date, the residents will begin to rotate at the applying hospital on or after the effective date of the increase. In addition, we note that section 1886(h)(9)(C)(ii) of the Act requires that if a hospital is awarded positions, that hospital must increase the number of its residency positions by the amount the hospital's FTE resident caps will increase, based on the newly awarded positions under section 126 of CAA. Therefore, we will require that a hospital must, as part of its application, attest to increase the number of its residency positions by the amount the hospital's FTE resident caps are increased based on any newly awarded positions in accordance with the provisions of section 1886(h)(9)(B)(i) of the Act.

(2) Determination of Hospitals That Are Located in a Rural Area or Are Treated as Being Located in a Rural Area (Category One)

Section 1886(h)(9)(B)(ii) of the Act requires the Secretary to distribute not less than 10 percent of resident positions available for distribution to each of four categories of hospitals. Under section 1886(h)(9)(B)(ii)(I) of the Act, the first of these categories consists of hospitals that are located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or are treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act. We refer to this category as Category One.

Section 1886(d)(2)(D)(ii) of the Act defines a rural area as any area outside a Metropolitan Statistical Area (MSA). Under the existing regulations at § 412.64(b)(1)(ii), an ''urban area'' means an MSA or a Metropolitan Division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by the Office of Management and Budget. Under existing § 412.64(b)(1)(ii)(C), a ''rural area'' means any area outside an urban area. Since FY 2005, we no longer use the term MSA, but instead use the term Core-Based Statistical Area (CBSA). Certain CBSAs are designated as urban, while those not designated as urban are considered rural. For purposes of section 1886(h)(9)(B)(ii) of the Act, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25504), we proposed that a hospital with its main campus located in an area outside of an urban CBSA would be considered a rural hospital. We note that this definition of ''rural area'' is consistent with our policy concerning designation of rural areas for wage index purposes.

Similar to our historical wage index policy of cross walking counties to CBSAs, CMS proposed to use the County to CBSA Crosswalk and Urban CBSAs and Constituent Counties for Acute Care Hospitals File, or successor files containing similar information, from the most recent FY IPPS final rule (or correction notice if applicable) to determine if a hospital is a rural hospital. (This file is available on the CMS website in approximately August of the year prior to the year of the application deadline. Under the file's current format, blank cells in Columns D and E indicate an area outside of a CBSA.)

Under section 1886(d)(8)(E) of the Act, a subsection (d) hospital (that is, generally, an IPPS hospital) that is physically located in an urban area is treated as being located in a rural area for purposes of payment under the IPPS if it meets criteria specified in section 1886(d)(8)(E)(ii) of the Act, as implemented in the regulations at § 412.103. Under these regulations, a hospital may apply to CMS to be treated as located in a rural area for purposes of payment under the IPPS.

Given the fixed number of available residency positions, it is necessary to establish a deadline by which a hospital must be treated as being located in a rural area for purposes of Category One. We proposed to use Table 2, or a successor table containing similar information, posted with the most recent IPPS final rule (or correction notice if applicable) to determine whether a hospital is reclassified to rural under § 412.103. If a hospital is not listed as reclassified to rural on Table 2, but has been subsequently approved by the CMS Regional Office to be treated as being located in a rural area for purposes of payment under the IPPS as of the application deadline for additional positions for the fiscal year, we proposed that the hospital must submit its approval letter with its application in order to be treated as being located in a rural area for purposes of Category One.

In this section we present a summary of the public comments and our responses to our proposals related to the determination of hospitals that are located in a rural area or are treated as

being located in a rural area (Category One).

Comment: Several commenters expressed support for our proposed definition of Category One hospitals.

Response: We thank the commenters for their support.

Comment: A commenter supported our proposed definition of a rural area, but suggested that we expand it to include certain locations within MSAs that are considered rural by the Federal Office of Rural Health Policy. The same commenter recommended that we assign a lower priority to geographically urban hospitals that have been reclassified as rural for wage index purposes, stating that this reclassification is done for payment equity purposes and does not make such facilities rural in any meaningful sense.

Response: Our proposed definition of a rural area is consistent with how that term is employed in the context of the Medicare statute. In particular, it is consistent with section 1886(h)(9)(B)(ii)(I) of the Act, as added by section 126 of the CAA, which refers specifically to the definition of a rural area at section 1886(d)(2)(D) of the Act. Furthermore, as we stated in the FY 2022 IPPS/LTCH PPS proposed rule, our definition is consistent with our policy concerning designation of rural areas for other purposes, including the wage index. For these reasons, we are not amending our definition of rural for purposes of section 126 of the CAA.

With respect to the commenter's second point concerning rural reclassifications, we believe that the commenter may have misinterpreted our proposal. The commenter referred specifically to urban hospitals that have been reclassified as rural for wage index purposes. We believe that the commenter was referring to hospitals that have been reclassified as rural by the Medicare Geographic Classification Review Board (MGCRB). Under section 1886(d)(10) of the Act, as implemented at 42 CFR 412.230, the MGCRB may change the classification of a hospital for purposes of the wage index only. However, the legislation directs the Secretary to consider hospitals that are treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act, which is a separate provision. Section 1886(d)(8)(E) of the Act, as implemented at § 412.103, is applicable beyond the calculation of the wage index. In particular, under § 412.103(a)(1), an urban hospital may apply to be reclassified as rural if it is located in a rural census tract of an MSA as determined by the Federal Office of Rural Health Policy. We believe that this is the same criterion that the commenter requested be consider in expanding our proposed definition of a rural area. Additionally, because section 1886(h)(9)(B)(ii)(I) of the Act references both hospitals that are located in a rural area (as defined in section 1886(d)(2)(D) of the Act) and those that are treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act, we read the statutory language as intending for both groups of hospitals to receive equal treatment.

With respect to hospitals that have reclassified as rural under § 412.103 (section 1886(d)(8)(E) of the Act), we note that consistent with our past application of rural reclassification to GME payment policies, these hospitals are considered rural for IME payment purposes and urban for direct GME payment purposes. However, we believe the inclusion of these hospitals under section 126 of the CAA is intended only to deem these hospitals as eligible recipients of the additional slots being distributed under section 126 of the CAA. We do not believe section 126 of the CAA limits urban hospitals that have reclassified as rural to only receiving IME FTE residency positions. As such, these hospitals are eligible for both direct GME and IME FTE residency positions under section 126 of the CAA.

Comment: Several commenters requested that we clarify whether rural referral centers are included in the definition of hospitals that are located in a rural area or are treated as being located in a rural area.

Response: Generally, in order to qualify for rural referral center (RRC) status under the criteria set forth at 42 CFR 412.96, a hospital must be rural, that is, either located in a rural area, or treated as being located in a rural area under section 1886(d)(8)(E) of the Act. Most RRCs would therefore qualify under Category One as defined previously in this final rule with comment period. However, we permit hospitals that previously qualified as an RRC but lost their status due to the Office of Management and Budget (OMB) redesignation of the county in which they are located from rural to urban to be reinstated as an RRC (August 1, 2000 IPPS final rule (65 FR 47054, 47089)). Currently, there are a relatively small number of hospitals with RRC status that are neither located in a rural area nor treated as being located in a rural area under section 1886(d)(8)(E) of the Act (approximately 11 percent). We are clarifying that such hospitals, despite their status as RRCs, would not qualify under Category One.

Comment: A commenter expressed concern that, as a result of our proposal to use the County to CBSA Crosswalk and Urban CBSAs and Constituent Counties for Acute Care Hospitals File, urban hospitals reclassified to rural may still be able to claim treatment as rural hospitals despite being located well within a CBSA. The same commenter also suggested what they characterized as a grammatical edit to our definition of rural for purposes of Category One. In the proposed rule, we proposed that a hospital with its main campus located in an area outside of an urban CBSA is a rural hospital. The commenter recommended that we revise this language to state that a hospital would be considered located in a rural area, or treated as such, if its main campus was located in an area outside of an urban CBSA and was classified as a rural hospital (that is, not reclassified as urban). The commenter added that this restriction would avoid allowing large urban rural referral centers to expand an existing program and take these residency positions from geographically rural hospitals, which would thwart what the commenter believes to be the legislative intent of the statute.

Response: We believe the commenter is referring to hospitals that are located in urban CBSAs and have been reclassified as rural under section 1886(d)(8)(E) of the Act, as implemented in the regulations at 42 CFR 412.103. As discussed previously, the statute explicitly refers to such reclassified hospitals among the categories of qualifying hospitals in section 1886(h)(9)(B)(ii)(I) of the Act. The preamble language cited by the commenter, and to which a grammatical edit was suggested, is only part of our proposed definition, which also includes hospitals reclassified as rural, as required by the statute. We further note that, as we proposed, such hospitals would not be identified using the County to CBSA Crosswalk and Urban CBSAs and Constituent Counties for Acute Care Hospitals File, but rather by consulting Table 2, or a successor table containing similar information, posted with the most recent IPPS/LTCH PPS final rule (or correction notice if applicable). If a hospital is not listed as reclassified to rural on Table 2, but has been subsequently approved by the CMS Regional Office to be treated as being located in a rural area for purposes of payment under the IPPS as of the application deadline for additional positions for the fiscal year, the hospital must submit its approval letter with its application in order to be treated as being located in a rural area for purposes of Category One.

It also appears that the commenter may have conflated two distinct

categories of hospitals, namely, urban hospitals reclassified as rural under § 412.103, and RRCs, which are governed by the regulations at § 412.96. While an urban hospital reclassified as rural may elect to apply for RRC status if it meets the criteria set forth at § 412.96, such assignment is not automatic, and many RRCs are in fact geographically rural. Thus, as explained previously, many, but not all, RRCs may qualify as rural hospitals for purposes of section 126 of the CAA, depending on whether they otherwise satisfy the criteria for Category One.

Comment: A commenter, located in an urban area within a largely rural state, requested that CMS reconsider our proposed definition of hospitals located in rural areas or treated as being located in rural areas. Another commenter, stated that despite being located in a rural area and serving a mostly rural population, they would not qualify under Category One since the zip code of the hospital itself is not located in a HPSA.

Response: In response to the first commenter, we refer to the language of section 1886(h)(9)(B)(ii)(I) of the Act concerning rural hospitals, and note that a hospital located in an urban area cannot qualify under this category (Category One) unless it has reclassified as rural in accordance with the regulations at 42 CFR 412.103. We believe that the second commenter has conflated our proposals regarding two distinct statutory categories, namely, Category One (rural hospitals) and Category Four (hospitals that serve HPSAs). In response, we are clarifying that a hospital located in a rural area, or that is treated as being located in a rural area, qualifies under Category One whether or not it is physically located in a HPSA.

Comment: A commenter requested that the states of Hawaii and Alaska, in addition to the U.S. territories of Guam, American Samoa, Commonwealth of the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands, be recognized as rural for any federal definition. The commenter stated that these areas face significant health care challenges as they are non-contiguous and distant from the rest of the United States, and that their health care systems are isolated and vulnerable.

Response: Designating the states of Hawaii and Alaska, in addition to the U.S. territories of Guam, American Samoa, Commonwealth of the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands, as rural for any federal definition is beyond the scope of this rulemaking. We note that hospitals in these states and territories that are located in a rural area or are treated as being located in a rural area, as applicable, are eligible to apply for residency positions under section 126.

Comment: A commenter stated that we should revise our proposed definition of Category One to include the requirement that the majority of residents' training should take place in a rural area. The commenter argued that, if the goal is to train more physicians to remain and serve in communities of need, then the greatest priority should be given to hospitals and systems that themselves are located in rural areas, and in fact serve rural communities. According to the commenter, this should include caveats that the training itself take place in a ''rural MSA,'' and residency positions should not be awarded to an organization that has a facility located in a rural MSA if that facility would not be the primary place of training.

Response: We agree with the commenter that the training and retention of physicians in rural and underserved areas is an important goal. However, the law requires that hospitals that are located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or are treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act are qualifying hospitals. Prioritization of applications is a separate issue from the definition of Category One (and is discussed in section II.B.3.d. of this final rule with comment period).

After review of the public comments received, we are finalizing our proposal regarding the determination of hospitals that are located in a rural area or are treated as being located in a rural area (Category One) as proposed, without modification.

(3) Determination of Hospitals for Which the Reference Resident Level of the Hospital is Greater Than the Otherwise Applicable Resident Limit (Category Two)

Under section 1886(h)(9)(B)(ii)(II) of the Act, the second category consists of hospitals in which the reference resident level of the hospital (as specified in section 1886(h)(9)(F)(iii) of the Act) is greater than the otherwise applicable resident limit. We refer to this category as Category Two.

Under section 1886(h)(9)(F)(iii) of the Act, the term 'reference resident level' means, with respect to a hospital, the resident level for the most recent cost reporting period of the hospital ending on or before the date of enactment of section 1886(h)(9) of the Act, December 27, 2020, for which a cost report has been settled (or, if not, submitted (subject to audit)), as discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25505).

Under section 1886(h)(9)(F)(iii) of the Act, the term 'resident level' has the meaning given such term in paragraph (7)(C)(i). That section defines ''resident level'' as with respect to a hospital, the total number of full-time equivalent residents, before the application of weighting factors (as determined under paragraph (4)), in the fields of allopathic and osteopathic medicine for the hospital.

Under section 1886(h)(9)(F)(i) of the Act, the term 'otherwise applicable resident limit' means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to the changes made by this provision of CAA 2021, but taking into account section 1886(h)(7)(A), (7)(B), (8)(A), and (8)(B) of the Act. These paragraphs all address the distribution of positions and redistribution of unused positions.

In the CY 2011 OPPS final rule with comment period, we previously interpreted these terms when we implemented section 5503 of the Affordable Care Act. Under section 1886(h)(8)(H)(i) of the Act (as interpreted in the CY 2011 OPPS final rule (75 FR 46391)), the ''reference resident level'' generally refers to the number of unweighted allopathic and osteopathic FTE residents who are training at a hospital in a given cost reporting period. That is, the ''reference resident level'' refers to a hospital's allopathic and osteopathic FTE resident count for a specific period. The definition can vary based on what calculation is being performed to determine the correct allopathic and osteopathic FTE resident count (see, for example, 42 CFR 413.79(c)(1)(ii)). As noted previously, section 126 of the CAA, under new section 1886(h)(9)(F)(iii) of the Act defines the ''reference resident level'' as coming from the most recent cost reporting period of the hospital ending on or before the date of enactment of the CAA (that is, December 27, 2020).

Under new section 1886(h)(9)(F)(i) of the Act, the term ''otherwise applicable resident limit'' is defined as ''the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph but taking into account paragraphs (7)(A), (7)(B), (8)(A), and (8)(B).'' In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25505), we proposed to define this as the hospital's 1996 cap during its reference year,

adjusted for the following: New programs as defined at § 413.79(e); participation in a Medicare GME affiliation agreement as defined at §§ 413.75(b) and 413.79(f); participation in an Emergency Medicare GME affiliation agreement as defined at § 413.79(f); participation in a hospital merger; whether an urban hospital has a separately accredited rural training track program as defined at § 413.79(k); applicable decreases or increases under section 422 of the MMA, applicable decreases or increases under section 5503 of the Affordable Care Act, and applicable increases under section 5506 of the Affordable Care Act.

Regarding the term ''resident level'', in the CY 2011 OPPS final rule (75 FR 46391) we indicated that we generally refer to a hospital's number of unweighted allopathic and osteopathic FTE residents in a particular period as the hospital's resident level, which we proposed to define consistently with the definition in section 126 of the CAA; that is, the ''resident level'' under section 1886(h)(7)(c)(i) of the Act, which is defined as the total number of full-time equivalent residents, before the application of weighting factors (as determined under paragraph (4)), in the fields of allopathic and osteopathic medicine for the hospital.

For the purposes of section 126 of the CAA we proposed that the definitions of the terms ''otherwise applicable resident level,'' ''reference resident level,'' and ''resident level'' should be as similar as possible to the definitions those terms have in the regulations at § 413.79(c) as developed in the CY 2011 OPPS rulemaking.

The following is a summary of the public comments and our responses to our proposals related to the determination of hospitals for which the reference resident level of the hospital is greater than the otherwise applicable resident limit (Category Two).

Comment: Several commenters expressed support for our proposed definition of Category Two hospitals.

Response: We thank the commenters for their support.

Comment: A few commenters requested that we clarify that a hospital qualifies under Category Two if it is over its direct GME cap, its IME cap, or both. Some commenters added that such an interpretation would be consistent with our implementation of the distribution process under section 5503 of Public Law 111–148.

Response: We are clarifying that a hospital qualifies for direct GME residency positions under Category Two if it is over its direct GME cap; qualifies for IME residency positions under Category Two if it is over its IME cap; and qualifies for both direct GME and IME residency positions if it is over both its direct GME and IME caps. Furthermore, we are clarifying that a hospital may only apply for direct GME and/or IME residency positions if it does not have sufficient room to start a new program or expand an existing program under its existing direct GME and/or IME caps, respectively. For example, if a hospital has sufficient room under its IME cap to expand an existing program, but not under its direct GME cap, that hospital may only apply for direct GME residency positions, but not IME residency positions, to facilitate the planned expansion.

Comment: A commenter expressed concern that Category Two may bias financing decisions toward larger hospitals that are more likely to be able to support residency positions in excess of their caps due to the training of more self-sustaining subspecialty physicians.

Response: While we acknowledge the commenter's concern, we note that hospitals training residents in excess of their otherwise applicable resident limit or caps, are included among qualifying hospitals as defined by the statute, which also requires that we distribute at least 10 percent of the aggregate number of additional residency positions to hospitals that qualify under this category.

After review of the public comments received, we are finalizing our proposal regarding the determination of hospitals for which the reference resident level of the hospital is greater than the otherwise applicable resident limit (Category Two) as proposed, without modification.

(4) Determination of Hospitals Located in States With New Medical Schools, or Additional Locations and Branch Campuses (Category Three)

The third category specified in section 1886(h)(9)(B)(ii) of the Act, as added by section 126 of CAA, consists of hospitals located in States with new medical schools that received 'Candidate School' status from the Liaison Committee on Medical Education (LCME) or that received 'Pre-Accreditation' status from the American Osteopathic Association (AOA) Commission on Osteopathic College Accreditation (the COCA) on or after January 1, 2000, and that have achieved or continue to progress toward 'Full Accreditation' status (as such term is defined by the LCME) or toward 'Accreditation' status (as such term is defined by the COCA); or additional locations and branch campuses established on or after January 1, 2000, by medical schools with 'Full Accreditation' status (as such term is defined by LCME) or 'Accreditation' status (as such term is defined by the COCA). We note that the statutory language is specific with respect to these definitions. We refer to this category as Category Three.

Based on research and assistance received from LCME and the COCA, we understand that each accrediting body administers a multi-step process for applicant medical schools to progress to fully accredited status within the first few years after they are established and begin training students. LCME grants candidate status to an applicant medical education program after it reviews and approves the medical school's data collection instrument and planning self-study; at this point, it determines that the school is ready for a survey visit, and the preliminary accreditation survey visit is scheduled. After that visit, LCME reviews the survey team's preliminary survey report and determines whether or not sufficient progress toward compliance with accreditation standards has been made and satisfactory plans for the medical education program have been developed.

If LCME grants preliminary accreditation status, the school may begin accepting applications for enrollment. During the second year of the school's charter class, a school with preliminary accreditation status may submit information and receive a survey site visit to determine whether it meets criteria for provisional accreditation status. Finally, LCME grants full accreditation status to schools with provisional accreditation status, typically in the fourth teaching year, after determining the school is in compliance with or has made significant progress toward attaining compliance with all full accreditation standards.

LCME defines a regional campus, comparable to ''additional locations and branch campuses'' in section 1886(h)(9)(B)(ii)(III)(bb) of the Act, as a site distinct from the main campus of the medical school where students spend at least 1 full year of the curriculum. Regional campuses of a medical education program receive accreditation status through the main campus of the program and are not separately accredited.

The COCA may grant pre-accreditation status to a proposed college of osteopathic medicine (COM) that has achieved candidate status and meets the standards of pre-accreditation status. The pre-accreditation process starts with the submission of a pre-

accreditation self-study by a proposed COM; COCA staff then reviews the submission and conducts a site visit to examine the proposed COM's compliance with accreditation standards. Following the site visit, the COCA reviews the site visit report and other submitted information and grants pre-accreditation status to a proposed COM that meets the pre-accreditation standards. Once a proposed COM receives pre-accreditation status, it may begin to recruit, accept applications from, and admit prospective students. We note that prior to 2017, the COCA used the term ''provisional status'' instead of ''pre-accreditation status.''

The COCA may grant accreditation status to a COM that has achieved pre-accreditation status and meets the standards for accreditation. These accreditation statuses include accreditation with exceptional outcome, accreditation, accreditation with heightened monitoring, accreditation with warning, and accreditation with probation. Any accreditation status constitutes full accreditation, in contrast to pre-accreditation status or candidate status, which do not constitute full accreditation status.

The COCA defines a branch campus as a geographically separate location apart from the COM's main campus that is: Permanent in nature; offers courses in educational programming leading to a doctorate in osteopathic medicine; has its own faculty and administrative or supervisory organization; and maintains its own budgetary and hiring authority. A COM that establishes a branch location must apply for and receive separate approval from the COCA; the application process has four steps: A written application and branch campus self-study, a progress report, a revised branch campus self-study and site visit, and a final, pre-operational site visit.

The COCA defines an additional location as a location that is geographically separate from the main campus of a COM, but unlike a branch location, shares administration, faculty, curriculum, and budgetary authority with the main campus. Additional locations receive accreditation through the main campus of the COM following the review of documents and a survey site visit, after which a COM may enroll students in the additional location.

Based on information gathered from LCME and the COCA about new medical schools, additional locations and branch campuses, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25506), we proposed that hospitals located in the following 35 States and 1 territory, referred to as Category Three States, would be considered Category Three hospitals: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Michigan, Mississippi, Missouri, Nevada, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Puerto Rico, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin. We further stated that if a hospital is located in a state not listed here, but believes the state in which it is located should be on this list, the hospital could submit a formal comment on the proposed rule to make a change to this list, or could provide documentation with submission of its application to CMS that the state in which it is located has a medical school or additional location or branch campus of a medical school established on or after January 1, 2000. Pursuant to the statutory language, all hospitals in such states are eligible for consideration; the hospitals, themselves, do not need to meet the conditions of section 1886(h)(9)(B)(ii)(III)(aa) or (bb) of the Act in order to be considered.

Comment: Several commenters expressed support for our proposed definition of Category Three hospitals.

Response: We thank the commenters for their support.

In addition, we did not receive any comments requesting that a state be added to the list of Category Three states.

Therefore, after review of the public comments received, we are finalizing our proposal regarding the determination of hospitals located in states with new medical schools, or additional locations and branch campuses (Category Three) as proposed, without modification.

(5) Determination of Hospitals That Serve Areas Designated as Health Professional Shortage Areas Under Section 332(a)(1)(A) of the Public Health Service Act (Category Four)

The fourth category specified in the law consists of hospitals that serve areas designated as health professional shortage areas under section 332(a)(1)(A) of the Public Health Service Act (PHSA), as determined by the Secretary. We refer to this category as Category Four.

The Health Resources and Services Administration (HRSA) designates certain areas as health professional shortage areas (HPSAs). Section 332(a)(1)(A) of the PHSA, states that a ''health professional shortage area'' is ''an area in an urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services) which the Secretary determines has a health manpower shortage''. HRSA designates HPSAs for primary care, mental health, and dental health.

A geographic area may be designated as a HPSA under section 332(a)(1)(A) of the PHSA only on the basis of a shortage of services for the entire population within that area (a ''geographic HPSA''). Subsequent clauses of 332(a)(1) refer to other types of HPSAs, to which we will return later in this final rule with comment period. The geographic area to which a geographic HPSA is assigned may be a single county, multiple counties, a county subdivision, census tract, or a group of census tracts.

As we noted in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25506), section 126 of the CAA does not explicitly address the question of how HPSAs for different medical specialties should factor into determining which hospitals serve areas designated as HPSAs. In our consideration of this question, we began by examining the use of HPSAs in the HPSA Physician Bonus Program authorized under section 1833(m) of the Act. This program is relevant because Congress established the program as an incentive to attract new physicians to medically underserved communities and to encourage physicians in those areas to remain there (69 FR 47517 through 47518).

The HPSA Physician Bonus Program was created by Section 4043 of the Omnibus Budget Reconciliation Act (OBRA) of 1987, which added section 1833(m) to the Act. It provides incentive payments to physicians who furnish services to an individual in an area that is designated as a HPSA. Originally, under section 1833(m) of the Act, a 5 percent payment was added, beginning January 1, 1989, to the amounts otherwise payable to physicians who furnish services to Medicare patients in designated HPSAs. Section 6102 of OBRA 1989 further amended section 1833(m) of the Act to raise the amount of this incentive payment from 5 percent to 10 percent for services furnished after December 31, 1990. The OBRA 1989 amendment also expanded eligible service areas to include both rural and urban HPSAs.

We first examined the role of primary care geographic HPSAs in the HPSA Physician Bonus program. Physicians furnishing services in a primary care geographic HPSA are eligible to receive the bonus payments and the payments apply to all physicians who perform covered services within a primary care

geographic HPSA, regardless of specialty. Similarly, section 126 of the CAA does not explicitly distinguish between physician specialties for purposes of allocating the additional residency positions. Therefore, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25507), we proposed that primary care geographic HPSAs would be considered in determining what hospitals qualify under Category Four and that hospitals that have main campuses or provider-based facilities in these HPSAs may apply for additional residency positions for any specialty. We also note CMS used primary care HPSAs for the allocation of residency positions for purposes of section 5503 of the Affordable Care Act (75 FR 72147).

We next considered the use under the HPSA Physician Bonus Program of areas that are solely mental health geographic HPSAs and not also primary care geographic HPSAs. We will refer to these areas as mental health only geographic HPSAs. The HPSA Physician Bonus Program provides incentive payments for services provided in mental health only geographic HPSAs, *but only for services provided by psychiatry provider specialties.* The distinction between primary care geographic HPSAs, in which all physician provider specialties, including psychiatry provider specialties, receive the incentive payments, and mental health only geographic HPSAs, in which only psychiatry provider specialties receive the incentive payments, is relevant to the question of how mental health only geographic HPSAs should factor into determining hospitals that serve areas designated as HPSAs for purposes of section 126 of the CAA. We believe that it is appropriate to incorporate this feature of the HPSA Physician Bonus Program as well, and proposed to use mental health only geographic HPSAs for mental health providers accordingly in the determination of hospitals that serve areas designated as HPSAs. Thus, we proposed that hospitals that only have main campuses or provider-based facilities in mental health only geographic HPSAs could only apply for residency positions for psychiatry residency programs.

We next considered dental geographic HPSAs. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of allopathic and osteopathic residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during the same cost reporting period is applied effective for discharges occurring on or after October 1, 1997. Given that dental residents are not included in this statutory cap and that section 126 of the CAA distributes additional residency positions in the context of the statutory cap, we did not propose that dental geographic HPSAs should factor into the determination of whether a hospital serves a HPSA for purposes of section 126 of the CAA.

In summary, we proposed to consider geographic HPSAs for primary care and mental health providers for purposes of determining hospitals that serve areas designated as HPSAs. We proposed that hospitals that only have campuses or provider-based facilities in mental health only geographic HPSAs could only apply for positions for psychiatry residency programs. We did not propose to consider dental HPSAs as dental FTE residents are not subject to a hospital's IME and direct GME caps.

We next considered what hospitals serving areas designated as primary care or mental health HPSAs means for purposes of Category Four. As with the question regarding the role of primary care, mental health, and dental HPSAs, section 126 of the CAA does not explicitly address this question.

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25507), there are many possible interpretations of what hospitals that serve areas designated as primary care or mental health HPSAs means for purposes of Category Four. The most expansive interpretation might be that this refers to the universe of hospitals where each hospital provides care to at least one patient that resides in a HPSA without regard to the location of the main campus of the hospital or of its other patient care locations. This interpretation could be made less expansive by developing a relative or absolute threshold for the number of patients of the hospital that reside in HPSAs. It could also be made less expansive by considering whether the physical location of the main campus of the hospital and/or its other patient care locations are inside of or proximate to a HPSA.

In considering this issue, we prioritized objective factors that would maximize distribution of GME positions to residency programs serving underserved populations. (See section V.J.2.a.(4). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule for a further discussion of our proposals for prioritizing care to underserved populations.) To this end, we proposed that a hospital could qualify under Category Four if it had its main campus or a provider-based facility (under 42 CFR 413.65) physically located in a primary care or mental health only geographic HPSA. Additionally, as part of the qualification requirements under Category Four, in the residency program for which the hospital was applying, we proposed that at least 50 percent of the residents' training time over the duration of the program would have to occur at those locations in the HPSA. We stated in the proposed rule that we believed it was important to avoid the possibility that a hospital with provider-based facilities in multiple locations, some of which may not be located in a HPSA, uses an additional residency position mostly or entirely to serve populations that face no health service shortage.

We proposed that a Category Four hospital submit an attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, that it has its main campus or a provider-based facility (under 42 CFR 413.65) physically located in a primary care or mental health only geographic HPSA, and in the program for which the hospital is applying, at least 50 percent of the residents' training time over the duration of the program occurs at those locations in the HPSA.

For example under our proposal, Hospital A applies under Category Four for a psychiatry residency program. Its main campus is located in a non-HPSA area and it has one provider-based facility located in a mental health only geographic HPSA. Hospital A must attest that residents training in the psychiatry residency program spend at least 50 percent of the duration of their training in the program at its provider-based facility located in the mental health only geographic HPSA.

As another example, Hospital B applies for a residency program. Its main campus is located in a primary care geographic HPSA and it has two provider-based facilities, one in the same geographic HPSA as the main campus and one in a non-HPSA area. Hospital B must attest that residents training in the program will spend at least 50 percent of the duration of their training in the program on the main campus or at the provider-based facility located in the geographic HPSA, combined (for example, 30 percent of the time on the main campus and 20 percent at the provider-based facility).

The following is a summary of the public comments and our responses to our proposals related to Category Four qualification requirements.

Comment: Many commenters objected to the proposed requirement that a hospital or provider-based facilities be located in a primary care or mental health only geographic HPSA to be eligible under Category Four. Several commenters expressed concern that our proposed definition of Category Four limits hospitals from eligibility and that as a result, only a small number of hospitals would qualify for residency positions awarded under section 126 of the CAA. Other commenters argued that this constraint does not take into account that many geographic HPSA residents rely on health services provided outside of their HPSA. A commenter noted this is particularly true of certain specialty care services, such as mental health services, for which HPSA-residing patients are referred to academic medical centers located in urban areas. Several commenters suggested that it is for this reason that the statutory language describes hospitals that serve HPSAs rather than explicitly limiting eligibility under this category to hospitals physically located within the geographic boundaries of HPSAs.

Many commenters believe Category Four should be interpreted to more generally include hospitals that play a meaningful role in providing health services to residents of shortage areas. These commenters suggested we modify our proposal to include both hospitals located within HPSAs and those within a reasonable distance of one. Several commenters provided specific recommendations on what would be considered within a reasonable distance of a HPSA, such as within one mile, 10 miles, 20 miles, and 25 miles. In addition, a commenter requested that CMS revise our proposed definition of Category Four so that a hospital may be eligible for section 126 of the CAA residency positions on the basis of serving either a geographic or ''population'' HPSA (the following link includes a brief description of HPSAs: *https://bhw.hrsa.gov/workforce-shortage-areas/shortage-designation#hpsas*). Another commenter noted that some underserved communities do not qualify for geographic or population HPSAs because of their proximity to wealthier areas, but face provider shortages that deserve recognition under Category Four. Some commenters recommended that we define Category Four in terms of the measure of the hospital's patient population that reside within geographic HPSAs, using either an absolute or proportionate threshold. A commenter requested flexibility in the data sources that hospitals may use to demonstrate they are serving or will at some point serve HPSA populations, including data from other government agencies and non-profit organizations.

Many commenters opposed the proposed requirement that to qualify under Category Four, at least 50 percent of residents' training time in the program must occur in facilities located in the geographic HPSA. According to some commenters, this requirement would impede teaching hospitals' ability to structure programs to best meet the needs of the patients and communities they serve as well as to satisfy administrative obligations, including accreditation standards. Commenters also stated that the requirement that 50 percent or more of residents' time be spent in a HPSA, often in rural areas, would not be possible since supervising physicians and training schedules must be focused on population centers with patient and condition mixes that are necessary for training. A few commenters explained that the proposed 50 percent requirement, in addition to the proposed requirement that hospitals or their facilities be physically located in a HPSA to qualify under Category Four, is too restrictive to meet the policy goal of directing new residency positions to areas that provide services to underserved populations and does not meet congressional intent.

Several commenters, while supporting the proposed requirement that 50 percent of resident training time in programs take place in locations in the HPSA, requested that nonprovider settings where hospitals may count training time for IME and direct GME purposes be counted. Commenters stated that community settings, such as critical access hospitals, Federally Qualified Health Centers (FQHCs), and rural health clinics (RHCs), are important contributors to the provision of services in HPSAs and to residency training. Several commenters added that, in their view, it was Congress's intent that FTEs awarded under section 126 of the CAA train at nonprovider settings in addition to hospital main campuses and provider-based facilities.

Several commenters were opposed to the proposed 50 percent training time requirement because they believe it would impose a recordkeeping burden on hospitals that administer residency programs. A few commenters noted that normally, resident rotations are reported in the Intern and Resident Reporting System (IRIS) in aggregate, whereas the proposed 50 percent training time requirement would demand individual resident tracking and reporting. Commenters stated that to attest to meeting the requirement, teaching hospitals would need to develop a new system and process to document and track section 126 of the CAA funded residents that is separate from the system and process used to track residents funded by other sources.

A commenter requested clarification on whether the proposed requirement that residents spend 50 percent or more of their training time in a geographic HPSA in order for the hospital to be eligible under Category Four is based on all residents in aggregate or to individual residents.

Response: We appreciate commenters' feedback and concerns regarding the eligibility requirements under Category Four. After further consideration, as discussed in greater detail later in this section, we are modifying certain aspects of our proposal in response to public comments. These modifications are intended to provide additional flexibilities in meeting these requirements, while still targeting Category Four eligibility to hospitals that are most clearly serving HPSAs. We are persuaded by commenters' arguments and agree that training in settings other than hospital settings is consistent with our goal of maximizing distribution of GME positions to residency programs serving underserved populations, including serving those in community settings, and should be counted toward meeting Category Four eligibility requirements. Therefore, we are modifying our proposal. Any and all program training that occurs in a geographic HPSA at scheduled program training sites that are physically located in that HPSA and treat the HPSA's population, including nonprovider settings and Veterans Affairs facilities, will count towards meeting the 50 percent training requirement to qualify under Category Four. In addition, because we are revising our proposed definition of Category Four to allow all of these settings to be qualifying training sites, an applicant hospital (including any provider-based facilities) itself will not be required to be physically located in a geographic HPSA in order to be eligible under Category Four as proposed. Rather, as long as the hospital participates in training residents in a program where at least 50 percent of the training time occurs at scheduled training site(s) that are physically located in a geographic HPSA, that hospital is considered to be eligible under Category Four. We believe these changes will provide additional flexibility for teaching hospitals to design programs to effectively serve patients and communities and meet any administrative requirements while

targeting Category Four eligibility to hospitals that are most clearly serving HPSAs.

Consider an example where Hospitals A, B, and C participate in training residents in an approved family medicine program. The program also has Training Site 1 as part of the rotation schedule (could be a nonprovider setting, a Veterans Affairs facility, or another community setting). Hospitals A and B are located in a primary care geographic HPSA as is Training Site 1. Hospital C is not located in the HPSA. Residents in the family medicine program spend 40 percent of their training time at Hospitals A and B, 40 percent of their training time at Hospital C, and 20 percent of their time training at Training Site 1. Since at least 50 percent of the program's total training time is spent training at facilities located in the primary care geographic HPSA, Hospitals A, B, and C all qualify under Category Four.

We appreciate commenters' suggestions to expand the proposed requirement for Category Four beyond a hospital's training sites that are physically located in HPSAs to include those within a certain distance of a HPSA. While we believe a distance or proximity threshold may warrant further consideration in the future for Category Four, we note the suggested distances by some commenters ranged anywhere between one mile to 25 miles. Based on these comments, a single uniform distance threshold may not always be appropriate in the context of section 126 of the CAA. For example, a single fixed mileage threshold may not equitably address tertiary care situations because hospitals providing equivalent tertiary care to residents of HPSAs may be located varying distances from those HPSAs. At this time, we believe the requirement that at least 50 percent of training time occurs at training sites that are physically located in a geographic HPSAs targets Category Four eligibility for hospitals that are most clearly serving HPSAs.

We also appreciate comments recommending that we consider the measure of a hospital's patient population that resides within a HPSA to determine whether a hospital serves a HPSA, as well as the suggestion of using different data sources to establish whether a hospital serves a HPSA. We believe there should be a consistent method used for hospitals to demonstrate that they meet the definition of Category Four. We note, simultaneously allowing the use of different data sources to establish whether a hospital serves a HPSA would mean that we might compare applications supported by different data collection methods, different definitions, or different data altogether. As discussed earlier, at this time we believe requiring that at least 50 percent of the training time of the program the hospital participates in occurs at training site(s) that are physically located in a geographic HPSA targets Category Four eligibility to hospitals that are most clearly serving HPSAs. However, we continue to welcome further feedback on the dependence of geographic HPSA residents on health services provided outside of their HPSA and are seeking comment on appropriate summary measures of where HPSA residents seek medical care as a feasible alternative for potential use in future rulemaking.

With regard to commenters' concern that the proposed definition of Category Four would limit the pool of eligible applicants relative to more expansive definitions, we appreciate the feedback. However, we do not believe the goal of Category Four should be to create the most expansive eligibility pool possible. Targeting Category Four eligibility to hospitals that are clearly serving HPSAs (as discussed previously) is entirely consistent with this statutory eligibility criterion and our policy objectives for section 126 of the CAA regarding medically underserved communities. In addition, as stated previously, we are seeking comments on potential alternative feasible definitions of Category Four to inform future rulemaking.

With regard to the request to include population HPSAs in the definition of Category Four, we note that section 1886(h)(9)(B)(ii)(IV) of the Act specifies that Category Four consists of hospitals that serve areas designated as health professional shortage areas under section 332(a)(1)(A) of the PHSA, as determined by the Secretary. Paragraph (A) of section 332(a)(1) of the PHSA describes a geographic HPSA, as explained previously and in the proposed rule (86 FR 25506). A population HPSA is described by paragraph (B) of section 332(a)(1), as explained in section II.B.3.d. of this final rule with comment period and section V.J.2.a.(4).(a). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25508). Therefore, we are not revising the definition of Category Four to include population HPSAs as requested by the commenter.

In response to comments that including a training time requirement for qualification falls outside of the legislative intent of section 126 of the CAA, we disagree. The statute at 1886(h)(9)(B)(2)(IV) limits Category Four eligibility to hospitals that serve areas designated as HPSAs under section 332(a)(1)(A) of the PHSA, as determined by the Secretary. As discussed in the proposed rule and in line with the Administration's support for advancing health equity in underserved communities, targeting Category Four eligibility to hospitals serving HPSAs is consistent with this statutory eligibility criterion and our policy objectives. We also note, as stated previously, we are seeking comment on potential alternative definitions of Category Four to inform future rulemaking.

We disagree with the comments that a minimum rotation time requirement imposes a significant tracking or reporting requirement. We do not expect hospitals to establish entirely new training tracks or administrative structures to accommodate FTE slots awarded under section 126 of the CAA. Hospitals regularly develop rotation schedules to facilitate residents' training at participating sites and a program's participating site information is generally readily available on the ACGME website. As such, we are specifying that the percentage of training time that residents in the program spend in the HPSA for purposes of Category Four is required to be substantiated, utilizing resident rotation schedules (or similar documentation). Regarding IRIS, we do not expect the existing reporting requirements to change for hospitals that receive these residential slots. We note that the 50 percent requirement applies to the program in its entirety, not to individual residents. As such, hospitals would not need to track the training time of individual residents to ensure each individual resident spends 50 percent or more of their training time in a geographic HPSA, so long as the program in its entirety meets the requirement.

Comment: Several commenters objected to our approach to address the issue of how specialties factor into determining which hospitals serve areas designated as HPSAs. Commenters stated that our use of the HPSA Physician Bonus Program as a model for addressing this question is flawed because hospitals do not respond to incentives and cannot relocate to new areas or establish new operations in the same manner as individual physicians and physician practices. Additionally, commenters stated that unlike the bonus payments in the HPSA Physician Bonus Program, the proposed size of the FTE awards will be insufficient to incentivize the establishment of new training programs in HPSAs.

Response: While we agree that the HPSA Physician Bonus Program and the Category Four eligibility of hospitals for additional GME residency positions target different types of entities, one being physicians and the other physician training programs, as we discussed in the proposed rule the policy objective underlying each is to strengthen the physician workforce in underserved areas. We therefore disagree with the comment that one is an unsuitable template upon which to build the other. However, as discussed in greater detail later in this section, we agree with commenters that the proposed 1.0 FTE per year limitation on FTE awards with no assurance of follow-on awards would be an insufficient incentive to encourage many hospitals to expand an existing or establish a new training program. As such, we are finalizing a policy to increase maximum award sizes to 5.0 FTEs per hospital per year, which we discuss in more detail in section II.B.3.c.(2). of this final rule with comment period.

Comment: Several commenters stated that hospital applications associated with mental health only geographic HPSAs should not be limited to psychiatry training programs. The commenters stated that provider shortages in mental health only geographic HPSAs are not limited to psychiatric services and the expansion of service availability in any specialty would help address community health care challenges.

A commenter objected to our inclusion of mental health only geographic HPSAs in the definition for Category Four. Instead, the commenter believed that eligibility under Category Four should only be met when a hospital's main campus or other facilities are in a primary care geographic HPSA. The commenter also stated that the new resident slots should only be used to fund training for primary care residents.

Response: We appreciate the comments requesting that hospitals not be limited to psychiatry training programs for hospitals that apply under mental health only geographic HPSAs for Category Four. While we understand that such an expansion could help address health care challenges in underserved communities, we have no direct evidence of a shortage of other specialties in mental health only geographic HPSAs nor do we have a method at this time to uniformly measure a shortage of other, non-psychiatric specialty providers in mental health only geographic HPSAs. As we discussed in the proposed rule and previously, the HPSA Physician Bonus Program provides incentive payments for services provided in mental health only geographic HPSAs, but only for services provided by psychiatry provider specialties. We continue to believe that it is appropriate to use mental health only geographic HPSAs for mental health providers in the determination of hospitals that serve areas designated as HPSAs. Therefore, we disagree with the comment that we should exclude mental health only geographic HPSAs from the definition of Category Four and limit residency positions to primary care training programs. However, we also believe it is equally important to advance health equity in physical and mental health services in underserved areas. Therefore, we are therefore modifying our policy in this final rule with comment period to include psychiatric subspecialty residency programs in addition to psychiatric residency programs within the mental health only geographic HPSA category.

Therefore, in this final rule with comment period, specific to mental health only geographic HPSAs, we are finalizing the policy that if a hospital participates in training residents in a psychiatric or a psychiatric subspecialty program, where at least 50 percent of the program's training time occurs in a training site(s) in the HPSA, the hospital is eligible under Category Four.

Comment: Several commenters expressed support for our proposed definition of Category Four hospitals.

Response: We thank the commenters for their support.

In summary, after consideration of and in response to the public comments received, we are finalizing our proposed requirements for determining eligibility under Category Four with modification in this final rule with comment period. Under our final policy, an applicant hospital qualifies under Category Four if it participates in training residents in a program in which the residents rotate for at least 50 percent of their training time to a training site(s) physically located in a primary care or mental health only geographic HPSA. Specific to mental health only geographic HPSAs, the program must be a psychiatric or a psychiatric subspecialty program. In addition, under this final policy, as proposed, a Category Four hospital must submit an attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, that it meets the 50 percent requirement. We did not receive any comments on our proposal not to consider dental HPSAs, as dental FTE residents are not subject to a hospital's IME and direct GME caps. We are finalizing that policy as proposed.

(6) Determination of Qualifying Hospitals

Section 1886(h)(9)(F)(ii) of the Act defines a qualifying hospital as a hospital described in any of the subclauses (I) through (IV) of subparagraph (B)(ii). As such, we proposed that a qualifying hospital is a Category One, Category Two, Category Three, or Category Four hospital, or one that meets the definitions of more than one of these categories.

The following is a summary of the public comments and our responses to our proposals related to the determination of qualifying hospitals.

Comment: A commenter supported our proposal for determining which hospitals are considered qualifying hospitals. Specifically, hospitals that meet the definitions of Category One, Category Two, Category Three, or Category Four, or hospitals that meet the definitions of more than one of these categories, are eligible for section 126 of the CAA residency positions.

Response: We thank the commenter for their support.

Comment: A commenter stated that the Department of Veterans Affairs should be included in future planning and evaluation of a more refined distribution approach for future years.

Response: We thank the commenter for the feedback. We note that residency positions distributed under section 126 will not be distributed to Veterans Affairs hospitals. These hospitals are eligible for GME payments through the Veterans Access, Choice, and Accountability Act GME Expansion. However, we note that when considering the percentage of program training time that occurs in a HPSA for purposes of section 126, training time occurring at a Veterans Affairs facility physically located in a HPSA will be included in that percentage.

Comment: Several commenters recommended adding eligibility criteria that would allow hospitals not meeting any of the definitions of Categories One through Four to qualify for residency positions awarded under section 126 of the CAA. Commenters recommended including the following eligibility categories: Small hospitals with fewer than 250 beds, hospitals with single residency programs, Indian health care providers, safety-net providers, and hospitals that host residency programs whose graduates later practice in either predominantly rural states or states with a large proportion of rational service areas designated as HPSAs.

Response: We appreciate the commenters' feedback and input on qualifying criteria. Section 1886(h)(9)(F)(ii) restricts eligibility to the four categories discussed previously. However, we agree with commenters that including hospitals with fewer than 250 beds in our final policy, may be useful in further prioritizing residency positions in certain instances. We refer commenters to the discussion in section II.B.3.d.(2). of this final rule with comment period, where we incorporate the suggested bed limit into our final policy. We also welcome further comment regarding whether the remaining priority hospitals or hospital characteristics identified by commenters should be addressed in other aspects of our policy in future years.

Comment: A commenter requested that we issue a list of hospitals that are likeliest to obtain additional residency positions under our finalized criteria. The commenter stated that advance signaling of which hospitals are likely to receive FTE awards will help them plan for contingent expansions of existing programs or establishment of new programs.

Response: We thank the commenter for the feedback. While we understand that significant planning resources are required to establish and expand training programs, we cannot anticipate changes to training program rotations between now and the start of the 2023 program year that will affect applications or predict which hospitals have determined that it is in their interest to expand their training programs with distributions under section 126 of the CAA and will apply. Therefore, we are unable to provide a list of hospitals that are likeliest to be awarded residency positions before awards are made. However, we intend to make available relevant information regarding the distribution of positions at the completion of the distribution process.

After consideration of comments received, we are finalizing our policy related to the determination of qualifying hospitals as proposed, without modification. Specifically, a qualifying hospital is a Category One, Category Two, Category Three, or Category Four hospital, or one that meets the definitions of more than one of these categories.

c. Number of Residency Positions Made Available to Hospitals and Limitation on Individual Hospitals

(1) Number of Residency Positions Made Available to Hospitals

Section 1886(h)(9)(A)(ii)(II) limits the aggregate number of total new residency positions made available in a single fiscal year across all hospitals to no more than 200. In order to provide these additional residency positions to hospitals as quickly as possible, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25508), we proposed to make 200 residency positions available for FY 2023 and each subsequent year.

In this section, we present a summary of the public comments and our responses to our proposals related to the number of residency positions made available to hospitals.

Comment: A number of commenters supported our proposal to make 200 residency positions available for FY 2023 and each subsequent year. A commenter recommended that we distribute all 200 residency positions each year even if fewer than 200 facilities apply, by allowing additional FTEs to be assigned to hospitals that do not apply; the commenter stated that this would fulfill the intent of Congress that 200 residency positions are distributed in each of the years.

Response: We thank the commenters for their support. With respect to the suggestion that we distribute all 200 residency positions each year even if fewer than 200 facilities apply, section 1886(h)(9)(A)(i) of the Act, as added by section 126 of the CAA, makes it clear that, in order to receive additional FTEs, a hospital must submit a timely application. The law does not grant us the authority to distribute residency positions to hospitals that do not apply. We also note that section 1886(h)(9)(A)(ii)(II) of the Act states that the aggregate number of residency positions made available shall not exceed 200 for a fiscal year; it does not require that all 200 residency positions to be distributed each year if there are insufficient numbers of applicant hospitals. Although we do not expect that there will be an insufficient number of applicant hospitals we intend to track progress in meeting all statutory requirements and evaluate the need for potential modifications in future rulemaking.

Comment: A few commenters expressed support for the statutory limit on the aggregate number of residency positions. Conversely, a commenter stated that the distribution of 200 residency positions per year across potentially 50 states will likely have minimal impact, particularly after a 25-year wait given that caps were implemented based on the number of FTE residents hospitals trained in 1996.

Response: The limit on the aggregate number of residency positions made available each year is set by the statute at 200.

Comment: A commenter was concerned about the impact of the distribution of residency positions under section 126 of the CAA on Medicaid. The commenter stated that the immediate impact on Medicaid in its state is unclear as it is uncertain how many of the new residency positions will be awarded to hospitals in its state. However, the commenter further noted that since hospitals awarded residency positions under section 126 will likely be incurring new medical education costs, Medicaid expenditures would increase.

Response: We are clarifying that residency positions under section 126 of the CAA are related to Medicare GME payments, not Medicaid. However, to the extent hospitals awarded residency positions under section 126 and the partial Medicare funding of new residency positions in that state might indirectly be associated with additional expenditures under that state's Medicaid program, any additional Medicaid expenditures that might occur are inestimable because it is unknown what hospitals in what states will apply and be awarded additional residency positions under section 126.

After consideration of comments received, we are finalizing our policy related to the number of residency positions made available to hospitals as proposed, without modification. Specifically, the aggregate number of total residency positions made available in a single fiscal year across all hospitals will be limited to no more than 200. Additionally, in order to provide these additional residency positions to hospitals as quickly as possible, we are making 200 residency positions available for FY 2023 and each subsequent year.

(2) Limitation on Individual Hospitals

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25508), we expect the demand from hospitals for the aggregate number of total residency positions made available for each fiscal year to significantly exceed the 200 maximum. For example, there are currently over 300 teaching hospitals that have their main campus located in a primary care or mental health only geographic HPSA. In that same proposed rule, we stated that we expect the majority of these hospitals

would apply for additional residency positions because they would qualify under our proposed Category Four. Even if we were to exclusively allocate the maximum 200 positions permitted under the statute each year to these hospitals, which are only a subset of Category Four hospitals (and Category Four itself is only one of four categories), it would still be insufficient to award even 1.0 FTE to each hospital each year. Therefore, in order to make additional residency positions available to more hospitals each year, we proposed to limit the increase in the number of residency positions made available to each individual hospital to no more than 1.0 FTE each year. We note that the proposal was not 1.0 FTE for each program at a hospital each year, but rather 1.0 FTE for each hospital each year.

As noted earlier, section 1886(h)(9)(C)(i) of the Act places certain limitations on the distribution of the residency positions, one of which is that a hospital may not receive more than 25 additional FTE residency positions. Under our proposed 1.0 FTE limitation per hospital per year, no hospital would receive more than 25 additional FTE residency positions. Rather, under the proposed 1.0 FTE limitation, hospitals would receive a maximum of 5 additional FTE residency positions.

The following is a summary of the public comments and our responses to our proposals related to the limitation on individual hospitals.

Comment: A commenter supported our proposal to limit the size of awards to 1.0 FTE per hospital per year. This commenter stated that the more stringent limit was warranted since the demand for additional residency positions will far exceed the total number of residency positions available, and applying a 1.0 FTE limit would promote the distribution of additional residency positions across a wider range of qualifying hospitals. Furthermore, the commenter recommended that, in subsequent distribution cycles, we prioritize applications from hospitals that have not yet received residency positions, so that no hospital would be awarded a second residency position until all other qualifying hospitals have received their first award.

Response: We thank the commenter for their support, however, as we explain in this section, we are modifying our policy in this final rule with comment period to allow hospitals to receive up to 5.0 FTEs per year. Regarding the recommendation that in subsequent distribution cycles, we prioritize applications from hospitals that have not yet received residency positions, we will take this recommendation under consideration for potential future rulemaking.

Comment: A commenter requested CMS clarify whether or not the proposal would distribute 1.0 FTE for the duration of a program, which equates to 3–5 residency positions per FTE, without requiring hospitals to reapply each year; for example, a hospital applying for a 3-year Family Medicine program would receive 3 residency positions total, while a hospital applying for a 5-year General Surgery program would receive 5 residency positions. Similarly, another commenter stated that they support our proposed limit and requested that in addition to the proposal, the FTE be financed for the duration of their training rather than a separate FTE being awarded for each year of training, and that this consideration be taken into account in determining the aggregate limit of 1,000 FTEs.

Response: We believe that the commenters have misconstrued our proposal, and that they are interpreting the term ''FTE'' to refer to the funding necessary to support one resident in each program year of a residency training program for the length of the program. On the contrary, the term ''FTE'' refers to the funding necessary to support one resident during a single year of training; this is the sense in which we employed the term in our proposal as written in the FY 2022 IPPS/LTCH PPS proposed rule, as well as in previous rulemaking cycles. We did not propose to distribute additional residency positions in blocks of 3.0–5.0 FTEs in the manner requested by the commenters. However, as we explain later in this section, we are modifying our policy in this final rule with comment period to allow hospitals to receive up to 5.0 FTEs per application year.

Comment: Many commenters strongly objected to our proposal to limit the size of awards to 1.0 FTE per hospital per year. Several commenters argued that the proposal is contrary to congressional intent, and that CMS was overstepping its authority by imposing a limit more stringent than what is specified in the law. Others stated that the proposed limit is inconsistent with the overall goal of increasing residency training levels, especially in rural areas, and that the proposal could significantly lessen the potential impact of the new legislation. A commenter worried that the nationwide physician shortage may be further exacerbated by the proposal to limit the size of awards to 1.0 FTE per year, and stated that it may not be capable of producing trained physicians to keep up with the need, if the cost burden for the residency training programs is not further shared with Medicare.

Many commenters argued that an award of 1.0 FTE per hospital per year would be insufficient to establish a new residency program or meaningfully expand an existing program. With respect to new programs, commenters observed that the ACGME Program Requirements specify a minimum complement of two to four residents in each program year for most specialties. They argued that the minimum cohort size is intended to ensure an appropriate learning environment and to provide residents with a sufficient shared clinical and educational experience that promotes peer learning, teamwork, and coordination of care. Accordingly, some commenters feared that the proposed limit would threaten program continuity and disrupt the training of residents. Moreover, a commenter observed that many programs are dependent on other specialties for the education of residents, and that the proposed limit would hinder an institution's ability to support new or expanded residency programs as a result of their inability to simultaneously expand residencies in the specialties that support those programs.

Several commenters were concerned that the proposed limit would not be economically feasible for many institutions, particularly smaller hospitals. A commenter estimated that five additional residency positions over 5 years might be sufficient to support some new fellowship programs, but would likely be insufficient to support even half of the FTEs for most new residency programs. Another commenter stated that receiving financial support for only one year of training would be untenable for most smaller institutions, and that only large hospitals with multiple programs could absorb the full cost of expanding a program by one resident per program year. Such considerations led a commenter to conclude that under our proposal the costs of starting or expanding a residency program would outweigh the benefits, while several others predicted that it would discourage small hospitals from submitting applications altogether.

Numerous commenters worried that the proposal would result in an onerous and unpredictable annual application process, which again would disproportionately burden smaller hospitals. They observed that hospitals would be forced to submit applications year after year with no guarantee of

receiving awards in subsequent rounds and thus no guarantee of being able to fund a residency position for the full length of a program. As an example, a commenter envisioned the scenario of a hospital that receives 1.0 FTE to establish a new residency program and does not qualify for additional residency positions in subsequent years; assuming a program duration of 3 years and a cohort size of four residents, such a hospital might be responsible for self-funding 11.0 additional FTEs in order to run the new program. Another commenter worried that hospitals may be forced to relocate residents if they are unable to secure funding for future years.

Several commenters also maintained that the proposed limit would particularly disadvantage hospitals in rural and underserved areas. A commenter stated that many such hospitals have consistently operated over their caps, often to their severe financial detriment; these hospitals are especially in need of financial assistance, and the proposed limit establishes a detrimental ceiling on the level of support they would be able to receive. As a result, the commenter concluded, our proposal would be likely to favor hospitals located in densely-populated urban areas. Another commenter added that an award of 1.0 FTE per year would risk limiting residency positions to existing programs, and would therefore disadvantage small institutions that are seeking to become teaching hospitals.

Commenters suggested various alternatives to our proposed limit of 1.0 FTE per hospital per year, with several saying that we should adhere to the statutory maximum of 25.0 FTEs. Among the most common recommendations was that we should tie the size of the award to the duration of the program for which a hospital is applying: For example, a hospital applying for a Family Medicine program would receive 3.0 FTEs total (1.0 FTE × 3 years of training), while a hospital applying for a General Surgery program would receive 5.0 FTEs (1.0 FTE × 5 years of training). Several commenters stated that this should be considered a minimum allocation, and expressed their preference for a maximum award of 15.0 FTEs total, which would allow a hospital to meaningfully expand one or more programs over 5 years. Other recommendations we received include: Distributing at least 3.0 FTEs per hospital per year; at least 3.0 FTEs per year for new programs, and 1.0 FTE per year for existing programs; at least 5.0 FTEs per year, with a commenter again suggesting that the amount could be different for new and existing programs; awarding residency positions in groupings or blocks of 4.0 FTEs; awarding up to 10.0 FTEs per hospital per year; and allowing hospitals to apply for up to three programs and no more than 15.0 FTEs each year.

Several commenters recommended that, if we retain the limit of 1.0 FTE per hospital per year, then we should streamline the application process to make it less burdensome and unpredictable for hospitals. All of these commenters suggested that hospitals that receive an award in a given fiscal year should be guaranteed to receive awards in subsequent application cycles, up to a certain minimum amount, which might be based on the duration of the training program. Such hospitals might be permitted to apply for all of their residency positions up front, without being required to submit further applications, or they might have the option of resubmitting less detailed applications in future years. Some commenters noted that under this model the minimum award might not be guaranteed in instances where a hospital initially applies for a program in one of the later application cycles, for example for FY 2026, assuming that all 1,000 residency positions are distributed over the course of 5 fiscal years. A commenter stated that, at a minimum, CMS should provide more clarity on the number of residency positions awarded over time to reduce the need for annual applications and to allow hospitals to better plan for their GME programs.

Response: We disagree with commenters who asserted that our proposed limitation of 1.0 FTE per hospital per year is contrary to congressional intent. Section 1886(h)(9)(C)(i) of the Act specifies that a hospital may not receive more than 25 additional full-time equivalent residency positions under the provisions of section 126 of the CAA; it does not specify a minimum award size, and leaves the Secretary broad latitude in determining the number of residency positions that will be distributed to individual hospitals.

However, after reviewing comments received, in particular the comments which expressed concern that our proposed limitation would be insufficient to establish a new program or meaningfully expand an existing program, that it would be impractical for many institutions, and that it would result in an unpredictable and burdensome application process, we have reconsidered our proposal. Therefore, in this final rule with comment period, we are modifying our proposal to adjust the size of the award to the length of the program for which a hospital is applying. Specifically, the maximum award amount is contingent on the length of the program for which a hospital is applying, with up to 1.0 FTE being awarded per program year, not to exceed a program length of 5 years or 5.0 FTEs. For example, a hospital applying to train residents in a program in which the length of the program is 3 years may request up to 3.0 FTEs per fiscal year.

We understand that in many cases a limit of 5.0 FTEs per hospital per year may not be sufficient for a hospital to fully fund Medicare's portion of a new program or planned expansion of an existing program; however, we believe that the increased limitation will provide a meaningful level of financial support to hospitals that would otherwise have to rely solely on their own resources to develop their GME infrastructure. Based on the comments we received, we believe that a limitation of 5.0 FTEs per hospital per year will be a sufficient amount to fully fund at least one resident in each program year for most specialties.

We note that if a hospital is applying for a program which has more than one participating site, the hospital should only request the FTE amount (not to exceed 1.0 FTE per program year) associated with the training time at its facilities (including any nonprovider settings consistent with 42 CFR 413.78).

Given the limited number of residency positions available and the number of hospitals expected to apply, our focus under this modification continues to be on hospitals that are applying to establish or expand a single residency program. Therefore, we are finalizing our proposal that a hospital may not submit more than one application in any fiscal year. We continue to expect that a hospital would choose to apply for a program that serves the HPSA with the highest score among its programs, but a hospital is not required to do so. Hospitals that receive awards in a given round of applications will be able to reapply in subsequent years, either for the same program or for a different program, but with no guarantee of receiving additional residency positions.

With respect to hospitals that are seeking to become teaching hospitals, we note that such hospitals are also eligible to establish a cap(s) under 42 CFR 413.79(e). We refer these hospitals to section II.B.5. of this final rule with comment period where we discuss the implementation of section 131 of the CAA, specifically the 1.0 FTE cost reporting threshold. We note that a

hospital that trains residents for the first time in an existing program or a new program will have a per resident amount (PRA) established for direct GME payment purposes, consistent with the regulations at 42 CFR 413.77(e). Such a hospital will also have a cap(s) established if the program in which it trains residents is a new program. We refer these hospitals to the August 31, 2012 **Federal Register** (77 FR 53416 through 53424), where we discuss the 5-year cap building period for new teaching hospitals.

Comment: Several commenters recommended that the limit on the number of residency positions should be adjusted to reflect the demonstrated need of individual hospitals. For instance, a commenter believed that hospitals in areas of great medical need should be allowed to receive more than 1.0 FTE per year; another commenter argued that, since the need for residency positions and full-time employees is not uniform across HPSAs, hospitals should not be subjected to a uniform cap on the size of their awards. A commenter stated that the limit should apply only to hospitals that do not qualify under any of the four statutory priority categories.

Response: We appreciate the commenters' concern for hospitals located in areas of high need, and believe these concerns are addressed by the statutory requirement which specifies that hospitals may qualify for additional residency positions by serving HPSAs, and that at least 10 percent of the aggregate number of residency positions should be distributed to hospitals in this category. In addition, as explained previously, we are modifying our policy in this final rule with comment period to allow hospitals to receive up to 5.0 FTEs per fiscal year.

With respect to the suggestion that the limit should apply only to hospitals that do not qualify under any of the four statutory priority categories, we note that section 1886(h)(9)(A)(i) of the Act directs the Secretary to distribute additional residency positions to qualifying hospitals, while section 1886(h)(9)(F)(ii) of the Act defines the term ''qualifying hospital'' as a hospital that satisfies the criteria of at least one of the four categories of hospitals described in subclauses (I) through (IV) of subparagraph (B)(ii). In other words, a hospital that does not qualify under any of the statutory categories would not be eligible to apply for and receive additional residency positions under section 126 of the CAA.

Comment: A few commenters recommended that CMS should delay the implementation of the proposed limitation on individual hospitals and evaluate the results of the first round of applications to determine whether a limit below the statutory maximum is warranted.

Response: As explained previously, we are modifying our policy in this final rule with comment period to allow hospitals to receive up to 5.0 FTEs per year. Under this modification to allow up to 5.0 FTEs, our focus continues to be a single program given the limited number of residency positions available and the number of hospitals we expect to apply. Therefore, we are finalizing our proposal that a hospital may not submit more than one application in any fiscal year. We continue to expect that a hospital would choose to apply for a program that serves the HPSA with the highest score among its programs, but a hospital is not required to do so. We plan to evaluate the results of the first round of applications and to consider whether any changes to the limitation on individual hospitals should be adopted in future rulemaking.

Additionally, as noted in the proposed rule and earlier in this section, section 1886(h)(9)(C)(i) of the Act places certain limitations on the distribution of the residency positions, one of which is that a hospital may not receive more than 25 additional FTE residency positions. Under our final policy to allow hospitals to receive up to 5.0 FTEs per year, no hospital would receive more than 25 additional FTE residency positions.

Comment: In considering our proposed limit of 1.0 FTE per hospital per year, a commenter stated that our proposal to prorate residency positions in case the number of hospitals with the same HPSA score exceeds the number of remaining residency positions will diminish the value of awards and increase the likelihood that the costs of creating a new program or expanding one would outweigh the benefits. Several commenters recommended that in case of a tie, rather than prorating residency positions, we should prioritize hospitals that are training residents in excess of their statutory FTE caps.

Response: We thank the commenters for their suggestions. As explained previously, we are modifying our policy in this final rule with comment period to allow hospitals to receive up to 5.0 FTEs per year. We refer the commenters to our discussion of our final policy to distribute residency positions, including our policy should there be a situation where the number of FTEs requested by hospitals with the same HPSA score, exceeds the number of remaining positions, in section II.B.3.d.(2). of this final rule with comment period.

In summary, we are modifying our proposal to account for the size of a hospital's award to the length of the program for which the hospital is applying, with a maximum award of 5.0 FTEs per hospital per year. We are also finalizing the portion of our proposal that a hospital may not submit more than one application in any fiscal year.

d. Prioritization of Applications From Hospitals for Residency Programs That Serve Underserved Populations

(1) Use of Geographic HPSAs and Population HPSAs

The Executive Order on ''Ensuring an Equitable Pandemic Response and Recovery'' noted that the COVID–19 pandemic has exposed and exacerbated severe and pervasive health and social inequities in America (see *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/21/executive-order-ensuring-an-equitable-pandemic-response-and-recovery/*.) As we stated in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25508), in order to help address these exposed health inequities longer term, we believe that it would be appropriate to prioritize the applications from hospitals that will use the additional residency positions under section 126 of the CAA in residency programs serving underserved populations.

This prioritization was already partially reflected in our proposed definition of Category Four, where we discussed maximizing the number of GME positions distributed to residency programs serving underserved populations in geographic HPSAs designated by HRSA under PHSA section 332(a)(1)(A). However, under PHSA section 332(a)(1)(B), HRSA also designates HPSAs on the basis of a shortage of services for a specific subset of the population (''population HPSAs'') rather than the entire population in an area as is the case in geographic HPSAs. These population subsets include, but are not limited to: Low-income populations, Medicaid-eligible populations, Native American populations, homeless populations, and migrant farmworker populations. (For information on the location and types of population HPSAs see *https://data.hrsa.gov/tools/shortage-area/hpsa-find*).

In order to more fully address health inequities for underserved populations, we believe that it also would be appropriate to prioritize the applications from hospitals that serve

the specific designated underserved population of a population HPSA.

We have already discussed our proposed definition in Category Four of hospitals that serve the populations of geographic HPSAs. Similar to that approach, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25508), we proposed that a hospital would be considered to serve a population HPSA if it has its main campus or a provider-based facility (under 42 CFR 413.65) physically located in a primary care or mental health population HPSA, and any such locations serve the designated underserved population of that HPSA. Additionally, we proposed that, as part of the qualification requirements under Category Four, in the residency program for which the hospital is applying, at least 50 percent of the residents' training time over the duration of the program must occur at those locations in the HPSA. As with geographic HPSAs, we believe it is important to avoid the possibility that a hospital with provider-based facilities in multiple locations, some of which may not be located in a population HPSA or serve the designated population of that HPSA, uses an additional residency position mostly or entirely to serve populations that face no health service shortage.

Also similar to our proposed use of geographic HPSAs, we proposed that hospitals that only have main campuses or provider-based facilities in mental health only population HPSAs may only apply for positions for psychiatry residency programs.

We proposed that a hospital submit an attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, that it has its main campus or a provider-based facility (under 42 CFR 413.65) physically located in a primary care or mental health population HPSA, any such locations serve the designated underserved population of that HPSA, and in the program for which the hospital is applying, the criterion that at least 50 percent of the residents' training time over the duration of the program occurs at those locations in the HPSA. We note that there is a difference between the Category Four qualification ''requirement'' and the prioritization ''criterion'' that 50 percent of a program's training time occur at training sites physically located in a HPSA. Section 1886(h)(9)(B)(ii)(IV) of the Act specifies that not less than 10 percent of the residency positions distributed shall go to hospitals that serve areas designated as HPSAs under section 332(a)(1)(A) of the Public Health Service Act, as determined by the Secretary (that is, geographic HPSAs, as discussed previously). Since section 1886(h)(9)(B)(ii)(IV) of the Act (referred to as Category Four in this preamble discussion) requires that not less than 10 percent of residency positions under section 126 of the CAA be awarded to hospitals that serve geographic HPSAs, our Category Four policy includes a ''requirement'' that the applicant hospital participates in training residents in a program in which the residents rotate for at least 50 percent of their training time to a training site(s) physically located in a primary care or mental health only geographic HPSA, as previously discussed. Separately, hospitals that qualify under categories One through Four are then subject to the prioritization criteria, including the ''criterion'' that at least 50 percent of a program's training time occur at facilities physically located in a geographic or population HPSA, as described in more detail later in this section. The HPSA training percentage under the prioritization ''criterion,'' while not required by statute, is consistent with the Administration's policy to prioritize training programs that have a higher likelihood of training physicians that will practice in underserved communities with the greatest need.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 22508 through 25509), we explained that our proposed approach for population-based HPSAs means that we potentially would be awarding a residency position for the provision of care that is not exclusively provided to the designated underserved population for which the shortage exists. However, in the context of our proposal to use HPSA scores to prioritize applications by the severity of the shortages, our proposal to limit the number of additional residency positions awarded to 1.0 FTE per hospital each year, and our proposed criterion that at least 50 percent of the training time over the duration of the program occur at locations in the HPSA that serve the designated underserved population of that HPSA, we believe it is sufficient for the residents in a program to provide care to the designated underserved population of that HPSA, and it is not necessary for residents to provide care exclusively to that population.

We note that HRSA also designates certain facilities as HPSAs under PHSA section 332(a)(1)(C) and the regulations at 42 CFR part 5. The process for facility HPSA designation is dissimilar from that for geographic and population HPSAs. Further, a HPSA score for a facility does not reflect on the adequacy of the health care workforce outside that facility in a geographic area, and so it is not comparable to geographic or population HPSAs. Therefore, we did not propose to use facility HPSA designations for the purposes of this rulemaking.

We also note that there are teaching hospitals that may not have facilities in areas designated as geographic or population HPSAs, but that under their Medicare provider agreement operate one or more facilities that serve areas for which there exists a shortage of providers. If this is the case, we recommend that a hospital interested in applying for FTE resident cap positions under this section contact its state or territorial Primary Care Office (PCO) to receive information on the HPSA designation process. HRSA maintains cooperative agreements with the 54 state and territorial PCOs, which conduct needs assessments and submit applications to HRSA to designate areas as HPSAs. We refer interested parties to 42 CFR part 5 and 57 FR 2473 for information on procedures for HPSA designation for primary care and mental health HPSAs, respectively.

In summary, we are finalizing without modification our proposal to prioritize applications from qualifying hospitals (that is, hospitals that qualify under categories One through Four, as previously described) for residency programs that serve underserved populations in geographic HPSAs or population HPSAs. In the next section we discuss our proposal and final policy for the use of HPSA scores for this purpose.

(2) Use of HPSA Scores for Prioritization

HRSA assigns HPSA scores on a scale of 0 to 25 as a measure of the severity of a primary care or mental health provider shortage in a geographic area, with higher scores indicating a more severe health professional shortage. As we observed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25509), using HPSA scores to differentiate applications from hospitals that qualify under categories One through Four would allow us to optimize the use of the limited number of additional residency positions under section 126 of the CAA and best address health inequities by focusing those residency positions on underserved populations with the most need.

In the proposed rule we stated that, in preparing its application for an additional residency position for a program, a hospital should refer to HRSA's HPSA Find Tool (*https://data.hrsa.gov/tools/shortage-area/hpsa-find*) to obtain the HPSA score of the HPSA served by the program and

include this score in its application. A HPSA is served by a program if that program meets the requirements discussed earlier. Given our proposal to limit the additional positions awarded to individual hospitals to 1.0 FTE for any given year, we proposed that a hospital may not submit more than one application in any fiscal year. Given the limited number of residency positions available and the number of hospitals we expect to apply, we expect that a hospital would choose to apply for a program that serves the HPSA with the highest score among its programs, but a hospital is not required to do so.

We proposed to allocate 1.0 FTE to each hospital with the highest HPSA score, prorating only in the event that the number of hospitals with the highest score exceeds the number of residency positions available. If the number of hospitals with the highest score is less than the number of residency positions available, each hospital with the next highest score would receive 1.0 FTE, with proration again occurring only in the event that the number of hospitals with this score exceeds the number of positions remaining. We would continue in this manner, moving on to hospitals with the next highest score until all available positions are distributed. We noted that, under this proposal, hospitals applying for residency positions for programs that do not serve HPSAs would not be categorically excluded, but those applications would have the lowest priority.

In the proposed rule we included the following as an illustrative example, assume the following hospitals apply, Hospitals A through HV. Assume there are 200 additional residency positions available. Under our proposal, Hospitals A through ET would each get 1.0 FTE, while Hospitals EU through HV would each get a prorated FTE award of 0.625, as follows:

Hospital name	HPSA score	FTEs awarded	FTEs distributed/ remaining
A–AX (50 hospitals)	25	1.0	50/150
AY–CV (50 hospitals)	24	1.0	50/100
CW–ET (50 hospitals)	21	1.0	50/50
EU–HV (80 hospitals)	19	0.625	50/0

In summary, we proposed that additional residency positions under section 126 of the CAA would be distributed to hospitals that qualify under categories One through Four based on the HPSA score of the HPSA served by the residency program for which each hospital is applying, with programs serving higher HPSA scores receiving higher prioritization. Hospitals applying for residency positions for programs that do not serve HPSAs would not be categorically excluded, but those applications would have the lowest priority.

In this section, we present a summary of the public comments and our responses to our proposals related to the prioritization of applications from hospitals for residency programs that serve underserved populations.

Comment: Some commenters expressed support for our proposal to use HPSA scores to prioritize applications from qualifying hospitals and the policy goal that underlies this approach, specifically that of addressing health disparities faced by underserved populations. Commenters supporting our proposal indicated that where residents train has an impact on where they practice. Some commenters stated that the proposed methodology is a fair approach to increasing access to care in rural and underserved areas. Some commenters indicated that the use of HPSA scores would help improve the distribution of physicians across the country.

Response: We thank the commenters for their support.

Comment: Some commenters agreed with CMS that a prioritization of applications by HPSA scores would likely result in the statutory minimum of at least 10 percent of total residency positions being awarded to each of the four categories in section 1886(h)(9)(B)(ii) of the Act. A commenter added that in the event minimum distributions to each category are not met, minor adjustments can be made to the methodology without substantially compromising the approach.

Other commenters disagreed and indicated that our proposed approach would not result in the minimum statutory distributions being met. For example, some of these commenters believed that our proposed prioritization approach might result in the minimum only being met for Category Four.

Response: We thank the commenters for their support. In response to the commenters that disagreed that our proposed approach would result in the minimum statutory distributions being met, we are finalizing our approach, as proposed, to collect information regarding qualification for all four categories in the application to allow us to track progress in meeting all statutory requirements, and evaluate the need to modify the distribution methodology in future rulemaking. However, we continue to believe that our proposed approach will most likely result in the statutory minimum 10 percent distributions being met for all four of the statutory categories by the end of the 5-year distribution process for the 1,000 FTE slots. Therefore, as described in more detail later in this section, we are finalizing our proposal that the residency positions will be distributed to qualifying applicant hospitals using a method that prioritizes allotments based on HPSA scores.

Comment: Many commenters objected to some or all of the aspects of the proposed criterion that at least 50 percent of a program's training time occur at applicant hospital locations inside a HPSA in order for CMS to use that HPSA's score to prioritize the section 126 of the CAA application for that program. Some of these commenters stated that nonprovider settings inside the HPSA that are not applicant hospital locations, such as FQHCs and RHCs, are important contributors to care in the HPSA and training time at these sites should count. Several of these commenters added that training time in nonprovider settings counts for other GME purposes.

Other commenters objected to the existence of a minimum training time criterion inside of a HPSA at all, regardless of what types of locations. These commenters argued that many HPSA residents rely on care provided outside of their HPSA. Some commenters noted this is particularly true for certain specialty care for which HPSA-residing patients are referred to teaching hospitals located outside the HPSA. Some of these commenters suggested we modify our proposal to include training locations within a HPSA and those within a reasonable

distance of one. Several commenters provided specific recommendations for a reasonable distance, such as within 1 mile, 10 miles, 20 miles, or 25 miles. A commenter requested that all Indian and Tribal facilities be considered for prioritization regardless of where they are located.

According to some commenters, a minimum training time inside the HPSA would impede teaching hospitals' ability to structure programs to best meet the needs of the patients and the communities they serve, as well as make it difficult to satisfy administrative obligations such as accreditation standards. For example, some commenters indicated it would be impossible for some programs to satisfy this criterion because locations in a HPSA provide insufficient training opportunities for some specialties, and we would force hospitals to operate programs in areas that are ill-suited to sustain training programs.

Some commenters were opposed to the minimum training time criterion because they believe it would impose a recordkeeping burden on hospitals. A few commenters noted that normally, resident rotations are reported in IRIS in aggregate, whereas the proposed 50 percent training time criterion would demand individual resident tracking and reporting. Commenters stated that to attest to meeting the criterion, teaching hospitals would need to develop a new system and process to document and track section 126 of the CAA funded residents that is separate from the system and process used to track residents funded by other sources.

A commenter requested clarification on whether the minimum training time criterion is based on all residents in a program in aggregate or to individual residents.

Response: We appreciate commenters' concerns regarding the proposed criterion that at least 50 percent of a program's training time occur at applicant hospital locations inside a HPSA in order for CMS to use that HPSA's score to prioritize the section 126 of the CAA application for that program. After consideration of these comments, we are modifying certain aspects of this prioritization criterion.

After considering the comments received, we agree with commenters that training should not be limited to hospital settings physically located in the HPSA to the exclusion of other settings physically located in the HPSA. For a geographic HPSA, any and all program training based on resident rotation schedules (or similar documentation) that occurs in the HPSA at program training sites that are physically located in the HPSA and treat the HPSA's population, including nonprovider settings and Veterans Affairs facilities, will count towards meeting the 50 percent training criterion. For a population HPSA, any and all program training based on resident rotation schedules (or similar documentation) that occurs in the HPSA at program training sites that are physically located in the HPSA and treat the HPSA's designated population, including nonprovider settings and Veterans Affairs facilities, will count towards meeting the 50 percent training criterion.

We disagree with commenters who objected to the existence of a minimum training time criterion inside of a HPSA at all. We acknowledge that many HPSA residents receive care provided outside of their HPSA in areas where the physician shortages are less severe. However, with the limited FTE slots available under section 126 of the CAA we are choosing at this time to prioritize in a clear way the care provided inside of HPSAs in order to increase the likelihood of residents choosing to practice in areas with more severe shortages. We seek comment to inform potential future rulemaking on incorporating a measure of care provided outside of a HPSA to HPSA residents into the section 126 of the CAA methodology.

We have considered the comment suggesting that all Indian and Tribal facilities be considered for prioritization regardless of where they are located. Given the unique relationship between the Medicare program and Indian and Tribal facilities, and the health care disparities that exist for the Indian and Tribal populations served by these facilities, we believe it would be appropriate to also prioritize applications for programs where the residents rotate into these facilities. Specifically, for purposes of prioritization we will allow the training time spent in Indian and Tribal facilities outside of a HPSA to count towards the minimum training time criterion for that HPSA, up to a maximum of 45 percentage points of the 50 percentage points required.

We disagree with the commenters who claimed that the minimum training time criterion inside the HPSA forces a hospital to restructure its residency programs or operate programs that include training opportunities in areas that cannot support them. Section 126 of the CAA is a voluntary program. Hospitals can choose to apply for additional residency positions or not. We developed a prioritization methodology because we anticipate that the number of FTE slots requested will exceed the number available. If that were not the case the minimum training time criterion would have no effect since even applications at the lowest priority level (that is, applications for programs that do not meet the minimum training time criterion for any HPSA) would receive the number of FTE slots requested assuming all other applicable requirements were met. We understand that some commenters disagree with a prioritization method based on HPSA scores, but that is different from the prioritization method forcing a hospital to restructure residency programs or operate them in areas that cannot support them.

As noted in responses to similar comments on Category Four, we also disagree with the comments that a minimum rotation time criterion imposes a significant tracking or reporting requirement. We are not requiring hospitals to establish entirely new administrative structures to accommodate section 126 of the CAA FTEs. Hospitals regularly develop rotation schedules to facilitate residents' training at participating sites and a program's participating site information is generally readily available on the ACGME website. As such, we are specifying that the percentage of time that residents in the program spend in the HPSA and in Indian and Tribal facilities (if applicable) for purposes of prioritization is required to be based on resident rotation schedules (or similar documentation).

Regarding IRIS, we do not expect the existing reporting requirements to change for hospitals that receive section 126 of the CAA FTEs. In response to the question regarding whether the minimum training time criterion applies to all residents in aggregate or to individual residents, the criterion applies to the program in its entirety, not to individual residents. As such, hospitals are not expected to track the training time of individual residents so long as the program in its entirety meets the criterion as demonstrated by the rotation schedule.

Comment: Many commenters expressed concern about the accuracy of HPSA scores and appropriateness of their use. Several commenters stated that HPSA scores are not the most precise measures of barriers to access to care or health care workforce shortages. A commenter provided a link to a letter they had written to HRSA on recommendations to improve their HPSA scoring methodology, including counting residents and physicians differently in the population to provider ratio, including an older-adult measure

in the primary care HPSA score, and taking steps to smooth out the volatility of HPSA scores to improve predictability for providers in shortage areas.[1] Another commenter provided a link to an academic article that argued HPSAs alone are an insufficient means to guide policies intended to address complex and interrelated health challenges.[2] Some commenters stated that the provider to population ratio is an important component of HPSA scores while the travel time to care outside of a HPSA is not. Some commenters argued that HPSA scores do not provide information on the availability of non-physician clinicians, such as nurse practitioners and physician assistants, or on the availability of non-primary care specialties, such as general surgery. Thus, according to the commenters, the HPSA score reflects an incomplete picture of physician availability in an area. A commenter claimed that some states game their HPSA scores or submit faulty data that incidentally lifts their scores. A commenter referenced HRSA's June 2020 RFI that sought ideas on improving its HPSA scoring methodology as an acknowledgment that the current system does not accurately capture local access to care challenges.

Response: We continue to believe that HPSA scores, while not a perfect measure, provide the best prioritization approach available at this time. They are transparent, widely used, publicly available, regularly updated, and have verifiable inputs for measuring the severity of a service area's need for additional providers. Consistent with the Administration's policy objectives and the authority provided to the Secretary under section 126 of the CAA, we have prioritized training programs that have a higher likelihood of training physicians that will practice in underserved communities with the greatest need.

With regard to the comment that HPSAs do not take into account the availability of non-physician clinicians in shortage areas, we believe that since the residency positions distributed under section 126 of the CAA are not available to non-physician clinicians, our focus should be on measuring physician shortages. In response to the commenters who expressed concerns related to HPSA scores being based on primary care specialties and not non-primary care specialties, we acknowledge this concern but note that the statutory Physician Bonus program utilizes primary care HPSAs for non-primary care specialties and we believe provides a currently feasible and appropriate template here.

Regarding the comment that claimed some states game their HPSA scores or submit faulty data that incidentally lifts their scores, the commenter did not provide any information to substantiate this claim.

We encourage stakeholders to continue to work with HRSA to improve HPSAs as part of its Shortage Designation Modernization Project (SDMP), which has been ongoing since 2013. We are also seeking comment on feasible alternatives to HPSA scores as a proxy for health disparities to inform potential future rulemaking regarding prioritization.

Comment: A commenter supported the use of geographic HPSA scores to prioritize applications, but opposed the use of population HPSA scores. The commenter indicated that population HPSA designations are sought by areas that do not meet the criteria for geographic HPSA designations and there are so many population HPSAs that their inclusion would undermine legislative intent to target the distribution of residency positions to areas with the greatest need.

Response: Although we agree with the commenter's assessment that the inclusion of population HPSA scores changes the prioritization of some applications, we disagree with the commenter that the inclusion of population HPSAs undermines targeting the distribution of FTE slots to areas of greatest need. The more targeted underserved populations in population HPSAs are as equally deserving as the broader populations in geographic HPSAs, and the HPSAs scores for both types of HPSAs reflect the severity of the need. We also note that in the case of a population HPSA, the requisite amount of training time for the residency program must occur at facilities that treat the underserved population of the population HPSA.

Comment: Several commenters argued that HPSAs are designed to inform about health professional shortages and do not reflect the capacity of hospitals to train residents.

Response: Our use of HPSA scores for prioritization is not intended to measure a hospital's capacity to train residents. We rely on a training program's ACGME accreditation and the ''demonstrated likelihood'' criterion for that information.

Comment: A commenter alleged that the example distribution table we provided in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25509) is invalid because the number of areas and specific HPSA scores represented in it do not reflect actual data. The commenter provided their own HPSA table that includes data from June 2020 and that indicates there are too few primary care geographic and population HPSAs with scores ranging from 21 to 25 to distribute all 1,000 residency positions to hospitals that serve those HPSAs if award sizes are capped at 1.0 FTE, so that the majority of the awards would be made to hospitals that serve HPSAs with scores below 21.

Response: The table provided in the preamble of the proposed rule was not designed to project the likely distribution of FTEs under section 126 of the CAA, but to illustrate how the prioritization methodology would be applied in practice based on hypothetical data. The minimum score for an application to receive sufficient prioritization to receive an award will not be known until all of the applications are received and evaluated for an application year.

Comment: A commenter stated that HPSAs can overlap and expressed concern that hospitals may have trouble locating their HPSA scores. The commenter cautioned that unless CMS posts a list of HPSA scores, hospitals will not be able to assess the impact on residency training and ultimately on patients' access to physicians. Another commenter stated that we should be more transparent about HPSA scores and clearer about how HPSA scores will be assigned to applicant hospitals. A commenter stated that they performed a study of the HPSA scoring methodology that found that rural and frontier areas with populations less than 5,000 people received lower scores. The commenter concluded that the HPSA scoring system discriminates against populations at that level or lower.

Response: A primary care HPSA, either a geographic or population one, cannot overlap with any other primary care HPSAs. Similarly, a mental health HPSA, either a geographic or population one, cannot overlap with any other mental health HPSAs. However, there are areas that are designated as both mental health and primary care HPSAs, and have different scores for each. Overlap between primary care and mental health HPSAs may be either complete or partial.

[1] *https://www.aha.org/system/files/media/file/2020/09/aha-comments-submitted-response-hrsas-rfi-health-professional-shortage-area-hpsa-scorin-9-18-20.pdf.*

[2] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7182224/.*

Hospitals can find information about the HPSA or HPSAs associated with their training program locations using the HRSA search tool at: *https://data.hrsa.gov/tools/shortage-area/by-address.* When a hospital finds that its residency training program meets the requirement to be prioritized by more than one HPSA, it may choose which HPSA to use on its application. A hospital cannot choose more than one HPSA to prioritize its application. CMS does not assign a HPSA to prioritize an application.

The HPSA scoring methodology is a relative measure that is applied uniformly and equitably regardless of the size of the underlying population. Hospitals that would like to learn more about how HRSA developed the HPSA scoring methodology through notice and comment rulemaking and how it calculates the HPSA scores can find out more by contacting HRSA or visiting this web page: *https://www.hhs.gov/guidance/document/hpsa-and-muap-hpsa-scoring-criteria.*

Comment: Several commenters requested that CMS clarify whether there is any difference in prioritization between primary care or mental health only geographic HPSAs and population HPSAs.

Response: There is no difference in prioritization with respect to the HPSA score of a primary care geographic HPSA, a mental health only HPSA, or a population HPSA. For example, a HPSA score of 21 is treated the same in the prioritization regardless of whether it is associated with a primary care geographic HPSAs, a mental health only HPSA, or a population HPSA.

Comment: Some commenters recommended other methods of prioritizing applications to distribute FTE slots to areas that are in most need. A commenter recommended prioritizing applications by a composite of HPSA scores and Medically Underserved Area (MUA) scores. Another commenter suggested that for the 60 percent of residency positions not required to be allocated to hospitals that meet the statutory eligibility categories, priority should be given to hospitals that are located in MUAs, or service areas or populations designated as medically underserved by state health entities. A commenter urged CMS to prioritize applications for addiction medicine in mental health only HPSAs. Other commenters requested that any program for any physician specialty be allowed to use the score from a mental health only HPSA, with preference given to applications for psychiatry training programs. A commenter stated that CMS should use the Medicare disproportionate share hospital (DSH) patient percentage of the applicant hospital to prioritize applications. Some commenters indicated that CMS should prioritize applications from small hospitals with less than 250 beds, and hospitals with only one residency program.

Response: We thank the commenters for their feedback. As indicated earlier, we continue to believe that HPSA scores, while not a perfect measure, provide the best prioritization approach available at this time. They are transparent, widely used, publicly available, regularly updated, uniformly calculated, and have verifiable inputs for measuring the severity of a service area's need for additional physicians. Different methodologies that would be used by individual states to designate areas or populations as underserved do not possess all of these characteristics.

We also do not believe that MUAs are as appropriate as HPSAs for purposes of section 126 of the CAA. HPSAs were designed for the National Health Service Corps to distribute clinicians to where they are needed most, they form the statutory basis for the Medicare Physician Bonus Program, and geographic HPSAs are explicitly referenced in section 126 of the CAA. In contrast, MUAs were designed to help establish health maintenance organizations and community health centers,[3] play no role in the Medicare Physician Bonus Program, and are not referenced in section 126 of the CAA.

We disagree that any residency training program regardless of specialty should be allowed to use the score from a mental health only HPSA for prioritization. These areas are only designated as shortage areas for mental health services and such a wide use would be broadly inconsistent with the Medicare Physician Bonus Program. Therefore, we are allowing only programs for Psychiatry and subspecialties of Psychiatry to use the score from a mental health only HPSA. We note that the subspecialties of Psychiatry include addiction psychiatry and multispecialty addiction medicine.

We disagree with the commenter who stated that CMS should use the Medicare DSH patient percentage of the applicant hospital to prioritize applications. We believe that using the DSH patient percentage is a less targeted way to increase the likelihood of residents choosing to practice in areas with more severe shortages.

We disagree with commenters who indicated that CMS should prioritize applications from small hospitals with less than 250 beds and generally smaller hospitals with only one residency program to the extent that the commenters meant irrespective of the HPSA scores associated with these applications. However, we do believe there is merit in considering smaller hospital size as a tiebreaker when prioritizing applications with equal HPSA scores in order to further reduce the impact of proration. Of the two suggestions by commenters, bed count is one of the most transparent and currently used measures of hospital size (42 CFR 412.105(b)). Therefore, if there are insufficient FTE slots remaining to distribute to applications with equal HPSA scores, we will first distribute FTE slots to applications from hospitals with less than 250 beds. If there are insufficient FTE slots to distribute to applications from hospitals with less than 250 beds, only then would we prorate among those applications. If there are sufficient slots to distribute to applications from hospitals with less than 250 beds, we would prorate the remaining slots among the applications from hospitals with 250 beds or more.

Comment: Several commenters who otherwise supported the HPSA scoring methodology recommended the incorporation of an ''impact factor'' that measures the proportion of residents that ultimately go on to practice in HPSAs. The use of this additional factor, according to commenters, would help ensure that section 126 of the CAA distributions support physician pipelines that produce lasting benefits for underserved areas. A commenter noted that one research-focused non-profit already documents the flow of residents to eventual practice locations for family medicine programs. Commenters also stated that the use of such an impact factor is aligned with the President's Executive Order on ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' which calls on federal agencies to recognize and address policies and programs that serve as barriers to equal opportunity. Another commenter expressed a similar view, that hospitals should be given priority if their training programs have records of sending residents on to practice in provider shortage areas.

Response: We thank the commenters for their feedback and agree that a measure of the extent to which residents later practice in underserved areas may be beneficial. In order to inform potential future rulemaking, we welcome further comment on how to best estimate the impact factor using appropriately comprehensive and

[3] *https://bhw.hrsa.gov/workforce-shortage-areas/shortage-designation#mups.*

transparent data sources across physician specialties, and how to weigh an impact factor in the prioritization.

Comment: A commenter expressed their opinion that if Congress passes new legislation increasing the number of available GME training residency positions, then the distribution process will need to be changed.

Response: Because we consider this comment to be outside the scope of the section 126 proposals, we are not directly responding to this comment in this final rule with comment period. However, we appreciate the commenter's concern and expect that any future changes following new legislation would be made through notice and comment rulemaking.

In summary, after considering the comments received, we are finalizing the following prioritization policy. Applications from hospitals for a fiscal year are grouped by the HPSA score of the application, with each grouping consisting of those hospitals with the same HPSA score. Applications are prioritized by descending HPSA score. Within each grouping, applications with equal priority (*i.e.,* those with the same HPSA score) are next grouped by whether the application is from a hospital with a bed size of less than 250 beds, or 250 beds or more. Applications from hospitals with less than 250 beds are prioritized within each grouping. The number of beds in the hospital is determined in accordance with § 412.105(b).

If there are insufficient slots available to be distributed to all applications with both the same HPSA score and the same bed size grouping, the remaining available slots are prorated among those applications.

e. Alternative Considered for Prioritization

As an alternative to our proposed prioritization approach, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25509 through 25510), we considered a simpler prioritization approach for FY 2023 that would allow additional time to work with stakeholders to develop a more refined approach for future years. Under this alternative approach, CMS would distribute 200 additional residency positions for FY 2023 among hospitals that qualify in Category One, Category Two, Category Three, and/or Category Four, with higher priority given to applications from hospitals that qualify in more categories. That is, hospitals that qualify under all four categories would receive top priority, hospitals that qualify under any three of the four categories would receive the next highest priority, then any two of the four categories, and finally hospitals that qualify under only one category. Under this alternative proposal considered, in the proposed rule, we stated that we would distribute 1.0 FTE to each hospital that qualified under all four categories, prorating only in the event that the number of hospitals that qualified under all four categories exceeds 200. If the number of hospitals that qualified under all four categories is less than 200, each hospital that qualified under three out of four categories would receive 1.0 FTE, with proration again occurring only in the event that the number of hospitals that qualified under three out of four categories exceeds the number of positions remaining. We would continue in this manner, moving on to hospitals that qualified under two out of four and one out of four categories until all 200 positions are distributed.

We sought comment on this alternative prioritization approach considered to allow for additional time to work with stakeholders to develop a more refined approach for future years.

Comment: Many commenters supported the proposed alternative prioritization approach. Commenters stated it would be less burdensome, more straightforward, and better reflect Congressional intent. Some commenters indicated this was similar to part of the approach used for Section 5503 of the Affordable Care Act. Several commenters indicated that CMS should only use the alternative method for FY 2023 and should work with stakeholders to develop a better approach for future years. Some commenters indicated that because the four eligibility categories are treated equally in the statute, hospitals that qualify under each one should be equally positioned to receive FTE slots. Several commenters stated that our proposed prioritization method based on HPSA scores would disadvantage many hospitals that qualify only under Category One, Category Two, and/or Category Three, and therefore would be contrary to Congressional intent. Some commenters indicated that for applications from hospitals that qualify under the same number of statutory categories under the alternative method, we secondarily prioritize those applications from hospitals training 10 FTEs or more above their caps, with those most above their cap receiving slots first.

Response: We thank the commenters for their feedback on the prioritization method described in the ''Alternatives Considered'' portion of the proposed rule.

We acknowledge that our proposed method based on HPSA scores prioritizes applications for programs where the residents spend significant time in a geographic or population HPSA. This is intentional. It is appropriate and entirely consistent with the statute for CMS to establish a sufficiently focused prioritization methodology so that our policy objectives for section 126 of the CAA regarding reducing health care disparities for medically underserved communities are most likely to be achieved. We disagree with commenters who believe our proposed prioritization method based on HPSA scores is not likely to achieve those goals. The locations of residents' training affects where they practice, as noted by other commenters. We acknowledge some similarity between aspects of the alternative approach and part of the approach taken in the implementation of section 5503 of the Affordable Care Act, but believe our approach based on HPSA scores is a more targeted improvement over section 5503's approach. We also note that as discussed earlier, the vast majority of commenters strenuously opposed our proposed 1.0 FTE limit per hospital and in response to those comments we are increasing that limit in this final rule with comment period.

We considered the comments that we should secondarily prioritize those applications from hospitals training 10 FTEs or more above their caps, with those most above their cap receiving slots first. We disagree with these comments because this secondary prioritization method would be less effective at increasing the likelihood of residents choosing to practice in areas with more severe shortages compared to using the method we are adopting for prioritization based on HPSA scores.

Comment: Some commenters opposed the use of the alternative method and indicated it would exclude hospitals in states that do not have new medical schools or additional locations and branch campuses from top priority, disadvantaging many rural states. Commenters stated that some of those states have made efforts to address physician workforce shortages by increasing medical school class sizes rather than establishing new medical schools. Some commenters stated that new allopathic medical schools train fewer family physicians than older medical schools so the alternative method disadvantages primary care.

Response: We agree with commenters that the alternative method would exclude hospitals in states that do not have new medical schools or additional

locations and branch campuses from top priority (that is, qualifying under all four categories) because those hospitals cannot qualify under Category Three. In addition, as several commenters pointed out, and as discussed earlier, section 126 of the CAA addresses a nationwide provider shortage and ensures minimum allotments to certain categories of hospitals; prioritization for all 1,000 residency positions distributed under this section to hospitals that meet all four statutory eligibility categories could lead to the possibility that hospitals located in the following 20 areas (15 states, one district and four territories) would be awarded zero positions: Alaska, American Samoa, Guam, Hawaii, Iowa, Maine, Maryland, Minnesota, Montana, Nebraska, New Hampshire, North Dakota, Northern Mariana Islands, Oregon, Rhode Island, South Dakota, U.S. Virgin Islands, Vermont, Washington DC, and Wyoming. We believe that prioritization according to the severity of the provider shortage is the more equitable approach to distribution. Therefore, after consideration of the comments received, and the reasons discussed, we are not finalizing the alternative methodology for FY 2023.

f. Distributing at Least 10 Percent of Positions to Each of the Four Categories

Section 1886(h)(9)(B)(ii) of the Act requires the Secretary to distribute at least 10 percent of the aggregate number of total residency positions available to each of the following categories of hospitals discussed earlier: Category One, Category Two, Category Three, and Category Four.

In the proposed rule (86 FR 25510), we stated that because it is possible for a hospital to be eligible for distribution of additional residency positions via more than one of the four categories, Category One, Two, Three or Four, there is a strong likelihood that by prioritizing applications by HPSA score the result will be that 10 percent or more of the additional residency positions will be distributed to hospitals in each of the four categories. In the proposed rule (86 FR 25510), we proposed to collect information regarding qualification for all four categories in applications to allow us to track progress in meeting all statutory requirements, and evaluate the need to modify the distribution methodology in future rulemaking.

We received no comments on this proposal. Therefore, we are also finalizing our plan as proposed to collect information regarding qualification for all four categories to allow us to track progress in meeting all statutory requirements, and evaluate the need to modify the distribution methodology in future rulemaking.

g. Hospital Attestation to National CLAS Standards

In order to ensure that the residents are educated and trained in culturally and linguistically appropriate policies and practices, we proposed that all applicant hospitals would be required to attest that they meet the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards) to ensure the section 126 of the CAA additional residency position allocation broadens the availability of quality care and services to all individuals, regardless of preferred language, cultures, and health beliefs. (For more information on the CLAS standards, please refer to *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53*)

Comment: Several commenters expressed support for our proposal that all applicant hospitals be required to attest that they meet the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care.

Response: We thank the commenters for their support.

Comment: A few commenters expressed support for the aims of the National CLAS Standards, but also raised concerns about requiring hospitals to attest to a uniform benchmark. A commenter argued that these criteria can be difficult to measure objectively, and recommended that CMS modify the application requirement so that hospitals are still eligible for residency positions if they attest that they support and are making progress toward meeting the National CLAS standards. Another commenter requested that hospitals be granted flexibility in demonstrating their commitment to culturally and linguistically appropriate training, and argued that many of the CLAS standards overlap with requirements that hospitals already meet, including the Internal Revenue Service (IRS) requirements for 501(c)(3) hospitals; the Joint Commission Standards related to language access and interpreter services; and ACGME core competency requirements. Another commenter cited similar requirements and provided several examples of initiatives that its own members have undertaken, but asserted that the concept of a national standardized or mandated curriculum is inappropriate, and that teaching hospitals should have the freedom to design and implement their own educational programs.

Response: We appreciate commenters' feedback and support. We acknowledge that other accreditation boards list some of the same requirements as the National CLAS standards requirements, but we believe that the National CLAS standards are more aligned with the Administration's commitment to addressing healthcare barriers, which include that residents are educated and trained in culturally and linguistically appropriate policies and practices. However, we will continue to consider further adjustments going forward if appropriate. For additional information about implementing the National CLAS standards within your organization to help advance and sustain culturally and linguistically appropriate services, please visit *https://thinkculturalhealth.hhs.gov/*.

After consideration of the comments we received, we are finalizing our proposal that all applicant hospitals would be required to attest that they meet the National CLAS Standards.

h. Payment for and Aggregation of Additional FTE Residency Positions Awarded Under Section 126 of the CAA

Section 1886(h)(9)(D) requires that CMS pay a hospital for additional positions awarded under this paragraph using the hospital's existing direct GME PRAs for primary care and OB/GYN programs and non-primary care programs consistent with the regulations at § 413.77. However, similar to our implementation of section 5503 in the CY 2011 OPPS final rule (75 FR 72192) with respect to the application of direct GME PRAs for primary care and nonprimary care residents, we proposed that a hospital that receives additional positions under section 126 of the CAA would be paid for FTE residents counted under those positions using the same primary care and nonprimary PRAs for which payment is made for FTE residents subject to the 1996 FTE cap.

We received no comments on our proposal that additional positions received under section 126 of the CAA would be paid using the same primary care and nonprimary care PRAs which are used with respect to FTE residents subject to the 1996 cap, therefore we are finalizing as proposed. We will revise Worksheet E–4 to add a line on which hospitals will report the number of FTEs by which the hospital's FTE caps were increased for direct GME positions received under section 126 of the CAA.

i. Conforming Regulation Amendments for 42 CFR 412.105 and 42 CFR 413.79

Section 126 of the CAA, under subsection (b), amends section

1886(d)(5)(B) of the Act to provide for increases in FTE resident positions for IME payment purposes as well. Specifically, a new section 1886(d)(5)(B)(xii) of the Act was added, stating that for discharges occurring on or after July 1, 2023, if additional payment is made for FTE resident positions distributed to a hospital for direct GME purposes under section 1886(h)(9) of the Act, the hospital will receive appropriate IME payment based on the additional residency positions awarded using the same IME adjustment factor used for the hospital's other FTE residents. We proposed conforming amendments to the IME regulations at 42 CFR 412.105 to specify that effective for portions of cost reporting periods beginning on or after July 1, 2023, a hospital may qualify to receive an increase in its otherwise applicable FTE resident cap if the criteria specified in 42 CFR 413.79(p) are met.

We received no comments on our proposed amendments to 42 CFR 412.105 to implement section 1886(d)(5)(B)(xii) of the Act with respect to IME payments. Therefore, we are finalizing our proposal to revise 42 CFR 412.105 by specifying that effective for portions of cost reporting periods beginning on or after July 1, 2023, a hospital may qualify to receive an increase in its otherwise applicable FTE resident cap if the criteria specified in 42 CFR 413.79(p) are met. We will revise Worksheet E Part A to add a line on which hospitals will report the number of FTEs by which the hospital's FTE caps were increased for IME positions received under section 126 of the CAA.

We also proposed to amend our regulations at 42 CFR 413.79 to specify that—(1) for portions of cost reporting periods beginning on or after July 1, 2023, a hospital may receive an increase in its otherwise applicable FTE resident cap (as determined by CMS) if the hospital meets the requirements and qualifying criteria under section 1886(h)(9) of the Act and if the hospital submits an application to CMS within the timeframe specified by CMS; and (2) FTE resident cap positions added under section 126 of the CAA (Pub. L. 116–260) may be used in a Medicare GME affiliation agreement beginning in the 5th year after the effective date of those FTE resident cap positions.

Comment: A commenter supported our proposal to allow residency positions added under section 126 of the CAA to be used in a Medicare GME affiliation agreement beginning in the 5th year after the effective date of the hospital's section 126 of the CAA award. Several commenters recommended additional regulatory action to ensure that after 5 years, residency positions remain allocated to programs where 50 percent of training takes place in a HPSA and be used for rural and primary care priorities. These commenters further recommended regulatory action to ensure that residency positions awarded under section 126 of the CAA not be repurposed for different strategic directions of the hospital. A commenter requested clarification whether residency positions, once awarded, are program-specific, and whether they may be used to support fellowships.

Response: We thank the commenters for their feedback. When a hospital applies for residency positions under section 126 of the CAA, it is attesting that the residency positions will be used for a specific program. Therefore, the residency positions awarded under section 126 of the CAA should be used for training residents in the program associated with the hospital's section 126 of the CAA application. Furthermore, section 126 of the CAA requires that not later than September 30, 2025, and again not later than September 30, 2027, the Comptroller General of the United States conduct a study and submit to Congress a report on the implementation of section 126 of the CAA.

In response to the comment that CMS take regulatory action to ensure that after 5 years the awarded residency positions are not being used for purposes other than those for which they were awarded, at this time, we are not including any additional requirements that must be met 5 years after the effective date of a hospital's section 126 award. However, we will consider additional guardrails for future rulemaking if residency positions awarded under section 126 are not being used for their intended purposes. In response to the question regarding fellowships, hospitals may apply for residency positions for fellowships under section 126.

After consideration of the comments we received, and for the reasons previously discussed, we are finalizing our proposed amendments to 42 CFR 413.79.

j. Prohibition on Administrative and Judicial Review

Section 126 of the CAA, under clause (c), prohibits review of section 1886(h)(9) of the Act. Specifically, it amends section 1886(h)(7)(E) of the Act by inserting ''paragraph (9),'' after ''paragraph (8),''. Therefore, we proposed that the determinations and distribution of residency positions under sections 1886(d)(5)(B)(xii) and 1886(h)(9) of the Act are final without administrative or judicial review.

We received no comments on the proposal that determinations and distribution of residency positions under sections 1886(d)(5)(B)(xii) and 1886(h)(9) of the Act are final without administrative or judicial review, and therefore are finalizing our proposed policy.

k. Report by the Comptroller General

We noted in the proposed rule that section 126(d) of the CAA requires the Comptroller General of the United States to conduct a study and submit to Congress two reports on section 126, after the 5-year period of implementation is complete. No comments were received regarding this requirement.

l. Application Process for Receiving Increases in FTE Resident Caps

In order for hospitals to be considered for increases in their FTE resident caps, each qualifying hospital must submit a timely application. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25510 through 25511), we proposed that an application would be considered timely for additional residency positions effective July 1 of a fiscal year if it is completely submitted by January 31 of the prior fiscal year. We also proposed that the following information be submitted on an application to be considered completely submitted:

- The name and Medicare provider number of the hospital.
- The name of the Medicare contractor to which the hospital submits its Medicare cost report.
- The residency program for which the hospital is applying to receive an additional position.
- FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report. (Including copies of Worksheets E, Part A, and E–4).
- If the hospital qualifies under ''Demonstrated Likelihood'' Criterion 1 (New Residency Program), which of the following applies:

☐ Application for approval of the new residency program has been submitted to the ACGME or the American Board of Medical Specialties (ABMS) by the application deadline for that year.

☐ The hospital has submitted an institutional review document or program information form concerning the new residency program in an application for approval of the new

program by the application deadline for that year.

☐ The hospital has received written correspondence by the application deadline for that year from the ACGME or ABMS acknowledging receipt of the application for the new residency program, or other types of communication from the accrediting bodies concerning the new program approval process (such as notification of site visit).

• If the hospital qualifies under ''Demonstrated Likelihood'' Criterion 2 (Expansion of an Existing Residency Program), which of the following applies:

☐ The hospital has approval by the application deadline from an appropriate accrediting body (the ACGME or ABMS) to expand the number of FTE residents in the program.

☐ The hospital has submitted by the application deadline an institutional review document or program information form for the expansion of the existing residency training program.

• Identification of the category that describes the hospital under section 126 of Division CC of the Consolidated Appropriations Act, 2021 (per section 1886(h)(9)(F)(ii) of the Social Security Act):

☐ (I) The hospital is located in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act) or is treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Social Security Act.

☐ (II) The reference resident level of the hospital (as specified in section 1886(h)(9)(F)(iii) of the Social Security Act) is greater than the otherwise applicable resident limit.

☐ (III) The hospital is located in a State with a new medical school (as specified in section 1886(h)(9)(B)(ii)(III)(aa) of the Act), or with additional locations and branch campuses established by medical schools (as specified in section 1886(h)(9)(B)(ii)(III)(bb) of the Act) on or after January 1, 2000.

☐ (IV) The hospital serves areas designated as health professional shortage areas (HPSAs) under section 332(a)(1)(A) of the Public Health Service Act, as determined by the Secretary.

• The HPSA (if any) served by the residency program for which the hospital is applying and the HPSA score for that HPSA.

• An attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, of the following:

''I hereby certify that the hospital is a Qualifying Hospital under section 126 of Division CC of the Consolidated Appropriations Act, 2021 (per section 1886(h)(9)(F)(ii) of the Social Security Act).

''I hereby certify the ''demonstrated likelihood'' that the hospital will fill the position made available under section 126 of Division CC of the Consolidated Appropriations Act, 2021 within the first 5 training years beginning after the date the increase would be effective, as determined by the Secretary (per section 1886(h)(9)(B)(i) of the Social Security Act).

''I hereby certify that the hospital agrees to increase the number of its residency positions by the amount the hospital's FTE resident caps are increased under section 126 of Division CC of the Consolidated Appropriations Act, 2021, if awarded positions (per section 1886(h)(9)(C)(ii) of the Social Security Act).

''I hereby certify that if the residency program for which the hospital is applying serves a geographic or population Health Professional Shortage Area (HPSA), that the hospital has its main campus or a provider-based facility (under 42 CFR 413.65) physically located in that HPSA, any such locations serve the designated underserved population of that HPSA in the case of a population HPSA, and in the residency program for which the hospital is applying, at least 50 percent of the residents training time over the duration of the program occurs at those locations in the HPSA.

''I hereby certify that the hospital meets the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards).

''I hereby certify that I understand that misrepresentation or falsification of any information contained in this application may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under federal law. Furthermore, I understand that if services identified in this application were provided or procured through payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result. I also certify that, to the best of my knowledge and belief, it is a true, correct, and complete application prepared from the books and records of the hospital in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding Medicare payment to hospitals for the training of interns and residents.''

We also proposed that the completed application be submitted to CMS using an online application system under development. A link to the online application system as well as instructions for accessing the system and completing the online application process will be made available on the CMS Direct GME website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME.*

Comment: Many commenters expressed concern that an award notification date as late as January 31 of the fiscal year of the FTE increase would leave teaching hospitals without the time needed to recruit resident candidates that would be funded with those awards, as the recruitment process begins several months earlier. Some commenters noted that January 31 is the last day that hospitals can amend their residency quotas for national resident matching purposes; they argued that, without knowing in advance how many residency positions they will receive under section 126, hospitals would have difficulty adjusting their program sizes for the purposes of matching with residents, which would affect their ability to recruit new residents to their programs.

Several commenters recommended approaches to better align the application and award process with the timing of accreditation decisions and the national residency matching timeline. Commenters also recommended flexibility where appropriate to accommodate differing fiscal years. All commenters that wrote about the notification date requested that it be moved forward and offered a range of alternative dates, from October 1 of the fiscal year in which the residency positions will be effective to no later than early or mid-December of the fiscal year the residency positions are effective. A commenter recommended postponing the application deadline for the first round to March 31, 2022.

Response: We appreciate commenters bringing this issue to our attention. We agree with the suggested date of March 31st as the application deadline. With regards to the date of the announcement of residency positions distributed under section 126, the Secretary is required to notify hospitals of the number of positions distributed by January 31 of the fiscal year of the increase. However, in light of the commenters' concerns, we will consider completing this announcement earlier if possible.

After incorporating the final policy described previously, in order to be considered for an increase in its FTE resident caps under section 126, each qualifying hospital must submit a

complete and timely application. An application is considered timely for additional residency positions effective July 1 of the applicable fiscal year if it is submitted by March 31 of the prior fiscal year. (For example, for awarded residency positions which will be effective July 1, 2023 (FY 2023), the completed application must be submitted by March 31, 2022 and hospitals will be notified of the increases they are awarded by January 31, 2023.) The following information must be submitted on the application in order for it to be considered complete:

- The name and Medicare provider number (CCN) of the hospital.
- The name of the Medicare Administrative Contractor to which the hospital submits its Medicare cost report.
- The residency program for which the hospital is applying to receive an additional position(s).
- FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report. (Including copies of Worksheets E, Part A, and E–4).
- If the hospital qualifies under ''Demonstrated Likelihood'' Criterion 1 (New Residency Program), which of the following applies:

☐ Application for accreditation of the new residency program has been submitted to the Accreditation Council for Graduate Medical Education (ACGME) (or application for approval of the new residency program has been submitted to the American Board of Medical Specialties (ABMS)) by March 31, 2022.

☐ The hospital has received written correspondence from the ACGME (or ABMS) acknowledging receipt of the application for the new residency program, or other types of communication concerning the new program accreditation or approval process (such as notification of site visit) by March 31, 2022.

- If the hospital qualifies under ''Demonstrated Likelihood'' Criterion 2 (Expansion of an Existing Residency Program), which of the following applies:

☐ The hospital has received approval by March 31, 2022 from an appropriate accrediting body (the ACGME or ABMS) to expand the number of FTE residents in the program.

☐ The hospital has submitted a request by March 31, 2022 for a permanent complement increase of the existing residency training program.

☐ The hospital currently has unfilled positions in its residency program that have previously been approved by the ACGME and is now seeking to fill those positions.

- Identification of the categories that describe the hospital under section 126 of Division CC of the Consolidated Appropriations Act, 2021 (per section 1886(h)(9)(F)(ii) of the Social Security Act):

☐ (I) The hospital is located in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act) or is treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Social Security Act.

☐ (II) The reference resident level of the hospital (as specified in section 1886(h)(9)(F)(iii) of the Social Security Act) is greater than the otherwise applicable resident limit.

☐ (III) The hospital is located in a State with a new medical school (as specified in section 1886(h)(9)(B)(ii)(III)(aa) of the Act), or with additional locations and branch campuses established by medical schools (as specified in section 1886(h)(9)(B)(ii)(III)(bb) of the Act) on or after January 1, 2000.

☐ (IV) The hospital serves an area designated as a health professional shortage area (HPSA) under section 332(a)(1)(A) of the Public Health Service Act, as determined by the Secretary).

- The HPSA (if any) served by the residency program for which the hospital is applying and the HPSA ID for that HPSA.
- An attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, of the following:

''I hereby certify that the hospital is a Qualifying Hospital under section 126 of Division CC of the Consolidated Appropriations Act, 2021 (per section 1886(h)(9)(F)(ii) of the Social Security Act).''

''I hereby certify the ''demonstrated likelihood'' that the hospital will fill the position made available under section 126 of Division CC of the Consolidated Appropriations Act, 2021 within the first 5 training years beginning after the date the increase would be effective, as determined by the Secretary (per section 1886(h)(9)(B)(i) of the Social Security Act).''

''I hereby certify that if my application is for a currently accredited residency program, the number of full-time equivalent (FTE) positions requested by the hospital does not exceed the number of positions for which the program is accredited.''

''I hereby certify that if my hospital currently has unfilled positions in its residency program that have previously been approved by the ACGME, the number of FTE positions requested by the hospital does not exceed the number of previously approved unfilled residency positions.''

''I hereby certify that if my application is for a residency training program with more than one participating site, I am only requesting the FTE amount that corresponds with the training occurring at my hospital, and any FTE training occurring at nonprovider settings consistent with 42 CFR 413.78.''

''I hereby certify that the hospital agrees to increase the number of its residency positions by the amount the hospital's FTE resident caps are increased under section 126 of Division CC of the Consolidated Appropriations Act, 2021, if awarded positions (per section 1886(h)(9)(C)(ii) of the Social Security Act).''

''I hereby certify that (choose one):

____ In the geographic HPSA the hospital is requesting that CMS use for prioritization of its application, at least 50 percent of the program's training time based on resident rotation schedules (or similar documentation) occurs at training sites that treat the population of the HPSA and are physically located in the HPSA.

____ In the population HPSA the hospital is requesting that CMS use for prioritization of its application, at least 50 percent of the program's training time based on resident rotation schedules (or similar documentation) occurs at training sites that treat the designated underserved population of the HPSA and are physically located in the HPSA.

____ In the geographic HPSA the hospital is requesting that CMS use for prioritization of its application, at least 5 percent of the program's training time based on resident rotation schedules (or similar documentation) occurs at training sites that treat the population of the HPSA and are physically located in the HPSA, and the program's training time at those sites plus the program's training time at Indian or Tribal facilities located outside of the HPSA is at least 50 percent of the program's training time.

____ In the population HPSA the hospital is requesting that CMS use for prioritization of its application, at least 5 percent of the program's training time based on resident rotation schedules (or similar documentation) occurs at training sites that treat the designated underserved population of the HPSA and are physically located in the

HPSA, and the program's training time at those sites plus the program's training time at Indian or Tribal facilities located outside of that HPSA is at least 50 percent of the program's training time.

____ None of the above apply.''

''I hereby certify that the hospital meets the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards).''

''I hereby certify that I understand that misrepresentation or falsification of any information contained in this application may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under Federal law. Furthermore, I understand that if services identified in this application were provided or procured through payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result. I also certify that, to the best of my knowledge and belief, it is a true, correct, and complete application prepared from the books and records of the hospital in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding Medicare payment to hospitals for the training of interns and residents.''

The completed application must be submitted to CMS using an online application system. A link to the online application system as well as instructions for accessing the system and completing the online application process will be made available on the CMS Direct GME website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME.*

We note that we have modified the application so that hospitals no longer need to furnish a HPSA score. Instead, when applicants include the HPSA ID associated with the geographic or population HPSA included in their application the HPSA score will automatically populate. In preparing its application for additional residency positions, hospitals should refer to HRSA's Find Shortage Areas by Address (*https://data.hrsa.gov/tools/shortage-area/by-address*) to obtain the HPSA ID of the HPSA served by the program and include this ID in its application. Using this HPSA Find Shortage Areas by Address, applicants may enter the address of a training location (included on the hospital's rotation schedule or similar documentation), provided the location chosen participates in training residents in a program where at least 50 percent (5 percent if an Indian and Tribal facility is included) of the training time occurs in the HPSA. Each year in November, prior to the beginning of the application period, CMS will request HPSA ID and score information from HRSA so that recent HPSA information is available for use for the application period. CMS will only use this HPSA information, HPSA ID's and their corresponding HPSA scores, in order to review and prioritize applications. To assist hospitals in preparing for their applications, the HPSA information received from HRSA will also be posted when the online application system becomes available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME.* The information will also be posted on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/IPPS-Regulations-and-Notices.* Click on the link on the left side of the screen associated with the appropriate final rule home page or ''Acute Inpatient—Files for Download.''

The burden associated with this information collection requirement is the time and effort necessary to review instructions and register for the electronic submission system as well as the time and effort to gather, develop and submit various documents associated with a formal request of resident position increases from teaching hospitals to CMS. The aforementioned burden is subject to the Paperwork Reduction Act (PRA); and as discussed in section III. of this final rule with comment period, the burden associated with these requests is captured in an information collection request currently available for public review and comment. The 60-day notice published on October 22, 2021 (86 FR 58664).

Lastly, we received public comments that were outside the scope of the GME proposals included in the FY 2022 IPPS/LTCH PPS proposed rule. These comments were related to: Medicare GME cap policies, promoting legislation to modernize and expand GME funding, incentivizing collaborative and team-based environments for health care practitioners, facilitating care delivery across states, funding for interprofessional primary care teams, rural recruitment and rotations for specialty residencies and fellowships, analysis of GME self-funding, large primary care group practices and preceptorships. Because we consider these public comments to be outside the scope of the proposed rule, we are not addressing them in this final rule. We may consider these public comments for possible proposals in future rulemaking.

4. Implementation of Section 127 of the CAA, ''Promoting Rural Hospital GME Funding Opportunity''

To encourage the training of residents in rural areas, section 407(c) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113) (BBRA) amended section 1886(h)(4)(H) of the Act to add a provision (subsection (iv)) stating that, in the case of a hospital that is not located in a rural area (an urban hospital) that establishes separately accredited approved medical residency training programs (or rural tracks) in a rural area, or has an accredited training program with an integrated rural track, the Secretary shall adjust the urban hospital's cap on the number of FTE residents under subsection (F), in an appropriate manner in order to encourage training of physicians in rural areas. Section 407(c) of Public Law 106–113 was effective for direct GME payments to hospitals for cost reporting periods beginning on or after April 1, 2000, and for IME payments applicable to discharges occurring on or after April 1, 2000. We refer readers to the August 1, 2000 interim final rule with comment period (65 FR 47026, 47033 through 47037) and the FY 2002 IPPS final rule (66 FR 39828, 39902 through 39909) where we implemented section 407(c) of Public Law 106–113. The regulations for establishing rural track FTE limitations are located at 42 CFR 413.79(k) for direct GME and at 42 CFR 412.105(f)(1)(x) for IME.

In the August 1, 2003 IPPS final rule (68 FR 45456 through 45457), we clarified our existing policy that although the rural track provision allows an increase to the urban hospital's FTE cap, sections 1886(h)(4)(H)(iv) and 1886(d)(5)(B) of the Act do not provide for an exclusion from the rolling average for the urban hospital for those FTE residents training in a rural track. These provisions are interpreted to mean that, except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, when an urban hospital with an FTE resident cap establishes a new rural track program or expands an existing rural track program, FTE residents in the rural track that are counted by the urban hospital are included in the hospital's rolling average calculation immediately. This policy is reflected in the regulation at § 412.105(f)(1)(v)(F) for IME and § 413.79(d)(7) for direct GME, and applies for IME and direct GME to cost

reporting periods beginning on or after April 1, 2000.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57027), we finalized a revision to the regulations at § 413.79(k) (and which, in turn, affect IME adjustments under § 412.105(f)(1)(x)) to permit that, in the first 5 program years (rather than the first 3 program years) of the rural track's existence, the rural track FTE limitation for each urban hospital would be the actual number of FTE residents training in the rural training track at the urban hospital, and beginning with the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural training track's existence, the rural track FTE limitation would take effect. However, as previously stated, due to the statutory language at sections 1886(d)(5)(B) and 1886(h)(4)(H)(iv) of the Act as implemented in our regulations at §§ 412.105(f)(1)(v)(F) and 413.79(d)(7), except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, FTE residents in a rural training track (RTT) program at the urban hospital are subject immediately to the 3-year rolling average for direct GME and IME. In addition, under the regulations at § 412.105(a)(1)(i), no exception to the IME intern- and resident-to-bed (IRB) ratio cap is provided for residents in a rural track training program (except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time).

Since implementation of the rural training track provision from the BBRA of 1999, stakeholders and advocates of residency training in rural areas have raised concerns about inequities and unintended consequences of the BBRA provision. First, the BBRA provision allows an urban hospital to receive additional cap slots based on the time that residents in the RTT train at the urban hospital. However, the provision does not specify that the Secretary provide a cap adjustment for rural hospitals participating in RTTs. As a result, unless the RTT program was new, the rural hospital could not receive FTE resident cap increases, resulting in direct GME and IME payments going only to the urban hospital for the urban portion of the training, with no attending funding going to the rural hospital for the rural portion of the training. Second, the statutory provision does not specify that the Secretary may provide a cap adjustment to urban hospitals or rural hospitals when an urban hospital adds additional rural locations to already existing RTTs. Third, the provision stated that the Secretary would adjust the caps of an urban hospital that establishes *separately accredited* approved medical residency training programs (or rural tracks) in a rural area. Historically, the Accreditation Council for Graduate Medical Education (ACGME) has separately accredited family medicine programs in the ''1–2 format'' (meaning, residents in the 1–2 format receive their first year experience at a core family medicine program in an urban area, and their second and third year experiences at another site, which may or may not be rural). Because the ACGME has historically accredited family medicine programs in the 1–2 format, CMS interpreted the provision to mean that the development of rural tracks in specialties other than family medicine may not be feasible. Fourth, residents added to an RTT were previously not exempt from the 3-year rolling average for IME and direct GME. We believe that section 127 of the CAA remedies each of these concerns, as we explain in more detail in this final rule with comment period.

a. Cap Adjustment for Urban and Rural Hospitals Participating in Rural Training Track Programs

As amended by the BBRA, section 1886(h)(4)(H)(iv) of the Act provided for IME and direct GME FTE resident cap adjustments for an urban hospital that establishes separately accredited rural tracks; however, the statute did not provide for a similar adjustment to rural hospitals participating in rural tracks. Specifically, section 1886(h)(4)(H)(iv) of the Act refers to the case of a *hospital that is not located in a rural area* but establishes separately accredited approved medical residency training programs (or rural tracks) in a rural area. Because of this explicit incentive and permission for FTE resident cap adjustments for an urban hospital that establishes a rural track, the rural track does not need to be new for Medicare payment purposes, as it otherwise would in order for the urban hospital to qualify for the FTE resident cap adjustments. That is, under section 1886(h)(4)(H)(iv) of the Act, if an urban hospital already had an accredited family medicine residency program, it could establish from that existing family medicine program, for the first time, a rural track, and, assuming all applicable requirements are met, that urban hospital could receive IME and direct GME FTE resident cap adjustments. However, with regard to a rural hospital participating in the second and third years of training in the rural track, since the BBRA language did not mention cap adjustments to rural hospitals, only if the program is new for Medicare payment purposes can the rural teaching hospital also receive an FTE resident cap adjustment for the program. Under § 413.79(e)(3), any time that a rural hospital participates in training residents in a new program, the rural hospital may receive an increase to its FTE resident caps. We refer readers to the FY 2010 IPPS/LTCH PPS final rule for the criteria identifying a new program for Medicare payment purposes (74 FR 43908 through 43917)). In this case, a rural track established from an already existing urban family medicine program would not meet the newness requirement for the rural hospital. Consequently, Division CC, section 127 of the CAA 2021 revised section 1886(h)(4)(H)(iv) of the Act to state that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural tracks) in a rural area, the Secretary must adjust in an appropriate manner the limitation under subparagraph (F) for such hospital *and each such hospital located in a rural area* that participates in such a training. This revision provides for cap adjustments for both the urban teaching hospital and the rural teaching hospital(s). In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25513), we proposed that each time an urban hospital and rural hospital establish an RTT program for the first time, even if the RTT program does not meet the newness criteria for Medicare payment purposes, both the urban and rural hospitals may receive a rural track FTE limitation. For example, Urban Hospital A has an existing internal medicine program. In July 2023, it partners with Rural Hospital 1 to create a RTT from the existing internal medicine program. We proposed that both Urban Hospital A and Rural Hospital 1 may receive adjustments to their resident caps (rural track FTE limitations) to reflect their portions of FTE residents training in the RTT. We proposed to make various changes throughout the regulations text at 42 CFR 413.79(k) ''Residents training in rural track programs'' to accommodate the rural track FTE limitations for both urban and rural hospitals. We also provide examples in this final rule with comment period, regarding how the rural track FTE limitations are calculated, according to the same methodology already in place at 42 CFR 413.79(k)(1) and as previously explained in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57028).

b. Cap Adjustments When the Urban Hospital Adds Additional Rural Training Tracks

As previously stated, under section 1886(h)(4)(H)(iv) *prior* to enactment of the CAA, if an urban hospital already had an accredited family medicine residency program, it could, for the first time, establish a rural track from that existing family medicine program and, assuming all applicable requirements were met, such hospital could receive the IME and direct GME FTE resident cap adjustments. Because section 1886(h)(4)(H)(iv) of the Act gave this explicit permission for FTE resident cap adjustments to an urban hospital that establishes a rural track, the rural track program does not need to be new for Medicare payment purposes in order for the urban hospital to qualify for the FTE resident cap adjustments. (We refer readers to the FY 2010 IPPS/LTCH PPS final rule for the criteria identifying a new program for Medicare payment purposes (74 FR 43908 through 43917)). However, after establishing its first RTT, the urban hospital can receive a rural track limitation adjustment for additional established RTTs only if those additional programs are ''new'' for Medicare payment purposes. As we explained in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25513), we believe that section 127 of the CAA amends section 1886(h)(4)(H)(iv) of the Act such that it permits us to adjust the resident caps of an urban hospital wishing to create additional RTTs *after establishing its first RTT,* while also adjusting the resident caps of the rural hospital(s) added by creating the subsequent RTTs. Section 127 of the CAA amends section 1886(h)(4)(H)(iv) of the Act to add a new subclause which states that for cost reporting periods beginning on or after October 1, 2022, in the case of a hospital not located in a rural area that *established or establishes* a medical residency training program (or rural tracks) in a rural area . . . adjust in an appropriate manner the limitation under subparagraph (F) for such hospital and each such hospital located in a rural area that participates in such a training. Because the law now states ''established or establishes,'' *both past tense and future tense,* we believe the statute grants the Secretary unique authority not previously held; that is, the authority to *prospectively* allow (under certain circumstances) cap adjustments to *existing RTTs expanded in a cost reporting period beginning on or after October 1, 2022.* That is, the provision gives explicit permission to adjust the RTT limitations of an urban hospital wishing to create additional RTTs *after establishing its first RTT,* while also adjusting the resident caps of the additional rural hospital(s) added by creating the second (or third, etc.) RTT. We believe this new statutory authority is separate and distinct from the statute's requirement that, for IME and direct GME payment purposes, *caps can be adjusted only for new teaching urban hospitals and for rural hospitals with new programs* under section 1886(h)(4)(H)(i) of the Act. That is, in general, urban hospitals becoming teaching hospitals for the first time and rural hospitals may receive cap adjustments only if the program(s) in which they train residents is ''new'' in accordance with Medicare rules (as explained in detail at 74 FR 43908 through 43917). Therefore, under the explicit authority under section 127 of the CAA, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25513) we proposed to prospectively allow increases to the IME and direct GME caps of both the participating urban and rural hospitals that *expand a qualifying RTT.* We proposed that if, in a cost reporting period beginning on or after October 1, 2022, an urban hospital with an existing RTT (''hub'') adds an additional RTT (''spoke'') to the existing urban core program of the same specialty, the urban and rural hospitals may receive adjustments to their rural track FTE limitation. (For ease of reference, we are referring to the urban core hospital as the ''hub'' and the one or more RTTs as the ''spokes'' associated with that urban ''hub.'') For example, Urban Hospital A has an existing family medicine program. In 2015, Urban Hospital A partnered with Rural Hospital 1 to create a RTT from the existing family medicine program and received a rural track FTE limitation to reflect the time that residents training in the RTT spent at its facility. In July 2023, Urban Hospital A partners with Rural Hospital 2 in a different rural area of the state, to create an additional family medicine RTT (adding another ''spoke'' to the existing urban program ''hub.'') We proposed that both Urban Hospital A and Rural Hospital 2 may receive adjustments to their resident caps (rural track FTE limitations) to reflect the portion of the time that FTE residents in the second family medicine RTT ''spoke'' spend at their respective facility. We believe that allowing prospective adjustments to RTT FTE limitations for additional RTT ''spokes'' added in cost reporting periods beginning on or after October 1, 2022 is an efficient means of addressing rural healthcare workforce shortages, by allowing already experienced and successful urban ''hub'' RTTs to branch out and partner with additional rural communities, rather than relying solely on starting RTTs from scratch. That is, with the ability for CMS to provide funding for additional spokes, it should be easier for urban hospitals that already have one RTT to reach rural areas more quickly and efficiently with the addition of more spokes, rather than starting brand new ''hubs''. However, we proposed to limit the increases to the urban and rural hospitals' RTT FTE limitations only in the instance where additional residents are recruited to add a *new rural* ''*spoke*'' *RTT,* and *not* to allow increases to the RTT FTE limitations in the instance where the urban and rural hospital add additional FTE residents to an existing rural RTT ''spoke.'' We believe it is appropriate to do so because section 127 of the CAA states that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural tracks) in a rural area or establishes an accredited program where greater than 50 percent of the program occurs in a rural area, the Secretary shall *consistent with the principles of subparagraphs (F)* and (G) and subject to paragraphs (7) and (8), prescribe rules for the application of such subparagraphs with respect to such a program and, in accordance with such rules, *adjust in an appropriate manner* the limitation under subparagraph (F) for such hospital and each such hospital located in a rural area that participates in such a training. That is, the statute directs the Secretary to adjust the cap (the limitation under subparagraph (F)) in an appropriate manner. As we explained in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25514), we believe that ''appropriate'' means not rendering the RTT FTE limitations meaningless. If we would allow adjustments to the RTT FTE limitations at any time, for any type or any amount of expansion even to already existing rural site ''spokes,'' there would, in essence, not be any RTT FTE limitation at all. As a matter of public policy, as long as the FTE resident caps (that is, the ''limitation under subparagraph (F)'') are in place, we believe that CMS should be judicious with providing for additional funded cap slots, as that, in turn, encourages thoughtful residency program expansion among hospital stakeholders. Therefore, we proposed to limit the provision of an increase to the urban and rural hospitals' RTT FTE limitations only to the instance where additional residents are recruited to add a new rural RTT ''spoke'' to the existing urban ''hub'', and *not* to allow increases

under this section to the RTT FTE limitations in the instance where the urban and rural hospital add additional FTE residents to an existing rural RTT ''spoke.'' As with the general FTE resident caps, since the slots associated with the RTT FTE limitation are fungible, urban and rural hospitals with multiple RTT ''spokes'' may reduce the number of FTE residents training at one track and ''spoke'' in order to accommodate an increase in training and funding at another track and ''spoke.'' For example, Urban Hospital A has an existing family medicine program. In 2015, it partnered with Rural Hospital 1 to create a RTT from the existing family medicine program. Urban Hospital A received a cap/rural track FTE limitation to reflect residents in the RTT training at its facility. In July 2023, Urban Hospital A receives permission from the ACGME to permanently expand this family medicine RTT by 2 FTE residents, to train at both Urban Hospital A and Rural Hospital 1. We proposed NOT to allow an adjustment to the rural track FTE limitation of Urban Hospital A and Rural Hospital 1 for the addition of 2 FTE residents, because this would be an expansion of an already existing RTT ''spoke.''

We also note that if the urban hospital already has an existing RTT in one specialty and an associated rural track FTE limitation, the urban hospital may also receive an adjustment to its rural track FTE limitation if it starts another RTT in a different specialty, because starting a RTT in a different specialty would not be an expansion of the already existing RTT. For example, Urban Hospital A has an existing family medicine program. In 2015, it partnered with Rural Hospital 1 to create a RTT from the existing family medicine program and, as a result, received a cap/rural track FTE limitation adjustment to reflect residents in the RTT training in its facility. In July 2023, Urban Hospital A partners once again with Rural Hospital 1 to create a RTT in internal medicine. We proposed that both Urban Hospital A and Rural Hospital 1 may receive adjustments to their cap/rural track FTE limitations to reflect the time that residents train in the internal medicine RTT ''spoke'' in their respective facilities. Thus, Urban Hospital A and Rural Hospital 1 would have cap/rural track FTE limitations reflecting FTE residents training in both a family medicine RTT and an internal medicine RTT.

c. Removal of Requirement That Rural Track Must Be ''Separately Accredited''

Previously, section 1886(h)(4)(H)(iv) stated that the Secretary would adjust the caps of an urban hospital that establishes *separately accredited* approved medical residency training programs (or rural tracks) in a rural area. Historically, the ACGME has separately accredited family medicine programs in the ''1–2 format'' (meaning, residents in the 1–2 format receive their first year experience at a core family medicine program, and their second and third year experiences at another site, which may or may not be rural). Because the ACGME has only accredited family medicine programs in the 1–2 format, hospitals have not been able to seek additional funding opportunities for rural tracks developed in specialties other than family medicine. Since implementation of the original BBRA provision, stakeholders have expressed concern that FTE cap adjustments have not been permitted for sending residents to rural areas if the program was not a separately accredited family medicine RTT. Section 127 of the CAA removes the requirement that the rural track be ''separately accredited.'' Specifically, section 1886(h)(4)(H)(iv)(II) now states that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural tracks) in a rural area, or establishes an accredited program where more than 50 percent of the training takes place in a rural area, the Secretary may adjust the resident cap in an appropriate manner. (Residency programs, whether they are ''rural tracks'' or any other program, must still be accredited under the law in order to receive IME and direct GME payments; see section 1886(h)(4)(H)(iv)(II) of the Act). Therefore, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25514), we proposed that effective for cost reporting periods beginning on or after October 1, 2022, so long as the program in its entirety is accredited by the ACGME, regardless of the specialty, it may qualify as an RTT and urban and/or rural hospitals may receive rural track FTE limitations, assuming all other requirements are met.

d. Requirement That Greater Than 50 Percent of the Program Occurs in a Rural Area

Under existing regulations at 42 CFR 413.79(k)(1) and (2), the urban hospital establishing the RTT may only receive a cap/rural track FTE limitation to count residents in the RTT if the urban hospital rotates residents to either a rural hospital or rural nonprovider site, for more than 50 percent of the duration of the program. As described in detail in rules implementing the original BBRA provision (see the August 1, 2000 interim final rule with comment period (65 FR 47033 through 47037) and the FY 2002 IPPS final rule (66 FR 39902 through 39909) where we implemented section 407(c) of Public Law 106–113), we adopted this greater than one-half duration rule based on the fact that residents training in separately accredited 1–2 family medicine RTTs spend greater than 50 percent of their training time in rural areas. We also wanted to ensure that cap adjustments would not be allowed for minimal rotations to rural areas. Section 1886(h)(4)(H)(iv)(II) is amended by section 127 of the CAA which states that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural tracks) in a rural area or *establishes an accredited program where greater than 50 percent of the program occurs in a rural area,* the Secretary shall, consistent with the principles of subparagraphs (F) and (G) and subject to paragraphs (7) and (8), prescribe rules for the application of such subparagraphs with respect to such a program. As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25515), we believe section 127 of the CAA now requires in statute what CMS has required in regulation; that is, we proposed that in order for urban or rural hospitals to receive FTE cap adjustments for residents training in RTTs, the residents must be in ''an accredited program where greater than 50 percent of the program occurs in a rural area.'' We believe that a ''medical residency training program (or rural tracks)'' refers to what the ACGME currently separately accredits as a 1–2 program; family medicine residencies that typically would have a first year in an urban hospital and second and third years in a rural hospital/setting. These separately accredited 1–2 family medicine RTTs may continue to maintain their RTT FTE limitations, assuming all applicable requirements are met. However, we proposed that an ''accredited program where greater than 50 percent of the program occurs in a rural area'' is the new statutory authorization for development of rural tracks in specialties *other than* family medicine, because eligibility for cap adjustments is no longer tied exclusively to ''separately accredited'', 1–2 programs. Specifically, as long as a program in its entirety is accredited by the ACGME, whether the program is in family medicine or in another specialty,

and the residents spend more than 50 percent of the entire program in a rural area, then prospectively for cost reporting periods beginning on or after October 1, 2022, we proposed to also provide additional slots to any program in any specialty. Therefore, for all accredited specialties, we proposed to allow an urban hospital to include in its FTE count, not to exceed its rural track FTE limitation, residents training in the urban hospital that are designated to rotate to a rural area for greater than 50 percent of the duration of the particular program. In addition, we proposed that a rural hospital that is partnered with the urban hospital in the RTT would similarly include in its FTE count, not to exceed its rural track FTE limitation, the time residents train in the rural hospital only if the residents rotate to a rural area for greater than 50 percent of the duration of the particular program. For example, greater than 50 percent of the duration of a 3-year family medicine program would be more than 18 months rotating to a rural area; greater than 50 percent of the duration of a 4-year psychiatry program would be more than 24 months training in a rural area.

e. Exemption From the 3-Year Rolling Average During the 5-Year Rural Track FTE Limitation Window

In the August 1, 2003 IPPS final rule (68 FR 45456 through 45457), we clarified our existing policy that although the rural track provision allows an increase to the urban hospital's FTE cap, sections 1886(h)(4)(H)(iv) and 1886(d)(5)(B) of the Act do not provide for an exclusion from the rolling average for the urban hospital for those FTE residents training in a rural track. These provisions are interpreted to mean that, except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, when an urban hospital with an FTE resident cap establishes a new rural track program or expands an existing rural track program, FTE residents in the rural track that are counted by the urban hospital are included in the hospital's rolling average calculation immediately. This policy is reflected in the regulation at § 412.105(f)(1)(v)(F) for IME and § 413.79(d)(7) for direct GME, and applies for IME and direct GME to cost reporting periods beginning on or after April 1, 2000.

In addition, as stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57028), under the regulations at § 412.105(a)(1)(i), no exception to the IME intern- and resident-to-bed (IRB) ratio cap is provided for residents in a rural track training program (except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, or for rural hospitals, if the rural track meets the definition of a new program).

As we explained in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25515), we believe that section 127 of the CAA amends section 1886(h)(4)(H)(iv) of the Act to provide for an exemption from the 3-year rolling average of the urban hospital and rural hospital during the 5-year growth window for FTE residents participating in rural tracks. Specifically, section 1886(h)(4)(H)(iv)(II) of the Act states that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural tracks) in a rural area or establishes an accredited program where greater than 50 percent of the program occurs in a rural area, *the Secretary shall consistent with the principles of subparagraphs (F) and (G)* and subject to paragraphs (7) and (8), prescribe rules for the application of such subparagraphs with respect to such a program. Subparagraph (F) is the FTE resident cap, and subparagraph (G) refers to the 3-year rolling average. This italicized language is the same as that used at section 1886(h)(4)(H)(i) regarding providing exemptions from the FTE resident cap and 3-year rolling average for new teaching hospitals starting new residency programs. That is, section 1886(h)(4)(H)(i) states: ''(i) New facilities.—The Secretary shall, *consistent with the principles of subparagraphs (F) and (G)* and subject to paragraphs (7) and (8), prescribe rules for the application of such subparagraphs in the case of medical residency training programs established on or after January 1, 1995.'' The previous rural track language at section 1886(h)(4)(H)(iv) did not mention subparagraph (G); therefore, the law did not exempt from the rolling average any residents participating in a rural track, even during the cap building window as we explained in the August 1, 2003 IPPS final rule (68 FR 45456 through 45457). Because section 127 of the CAA amends section 1886(h)(4)(H)(iv) to add in new subclause (II) which contains language modeled on the language for providing for FTE resident cap and rolling average exemptions in the case of new programs started on or after January 1, 1995, we proposed that similarly, during the 5-year cap growth window for RTTs, the FTE residents participating in the RTT either at the urban hospital or a rural hospital would not be included in a hospital's 3-year rolling average calculation during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each rural track. That is, just as residents in new programs are exempt from the 3-year rolling average until the cost reporting period that coincides with or follows the start of the sixth program year, similarly, effective for RTTs started in cost reporting periods beginning on or after October 1, 2022, for each rural track started, full-time equivalent residents at an urban hospital or rural hospital in a rural track program would be excluded from the rolling average calculation during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each rural track.

f. Changes to the Regulations Text

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25516), although section 127 of the CAA directly amends section 1886(h) for direct GME, and does not specifically refer to amendments for IME, the existing language at section 1886(d)(5)(B)(viii) of the Act states that rules similar to the rules of subsection (h)(4)(H) shall apply for purposes of clauses (v) and (vi). Accordingly, the statutory authority to make corresponding changes to IME for rural tracks already exists. Clause (v) refers to the IME resident caps, and clause (vi) refers to the 3-year rolling average. Therefore, we proposed to apply to the IME payment the new authority under section 1886(h)(4)(H)(iv) of the Act to allow both urban and rural hospitals to receive IME rural track FTE limitations, as well as an exemption from the IME 3-year rolling average for FTE residents during the 5-year cap building window. We are making appropriate changes to the regulations text for IME at 42 CFR 412.105(f)(1)(v)(F) and 412.105(f)(1)(x) to mirror the following proposed regulations text changes for direct GME:

- We proposed to modify the definition of Rural Track FTE limitation at 42 CFR 413.75(b) to add ''or rural hospital.''
- We proposed to remove the requirement at 42 CFR 413.79(d)(7) that FTE residents in the rural track are included in the 3-year rolling average during the 5-year cap building window.
- We proposed to make various changes throughout the regulations text at 42 CFR 413.79(k) ''*Residents training in rural track programs.*''

g. Documentation Required for Medicare Administrative Contractor (MAC) To Pay for RTTs

We will amend or clarify as necessary the Medicare cost report, CMS–2552–10, Worksheets E, Part A for IME and E–4 for direct GME, to accommodate additional rural track limitations. With this new authority to pay for more Rural Track Programs (RTPs—see explanation in response to comments later in this section as to why CMS is using the term ''RTP''), MACs may face an increase in requests for adjustments to interim rates as hospitals first build these programs. While, as with payment for any GME program, hospitals must maintain and, upon a MAC's request, submit applicable documentation, to make review and processing of these new RTP payment requests more manageable, we are reiterating the documentation requirements here. We proposed that the urban and rural hospitals must provide, upon request, to its MAC the following (Note: In response to a comment we received on the following bullet points, we have modified the language in these bullet points to reflect our response to that comment in this final rule with comment period):

- The ACGME accreditation for the program as a whole (that is, both urban and rural training components), and documents showing whether the urban and rural participating sites are starting the RTP for the first time in this particular specialty, or whether the urban and rural hospital already have an RTP in this specialty, but are adding additional participating sites to the RTP.
- A list of all urban and rural hospital and nonprovider training sites in the RTP.
- Resident rotation schedules (or similar documentation) showing that residents in the specified RTP spend greater than 50 percent of their training in a geographically rural area in the 5-year growth window in order to receive IME and direct GME rural track FTE limitations. In the instance where only a subset of the residents in the particular program are participating in the RTP, and the training time of the RTP residents is included in the main rotation schedule for the entire program, the hospital must specifically highlight the names of the residents and their urban and rural training locations on the main rotation schedule, so that the MAC can easily identify which residents are training in the RTP, where they are training, and be able to verify that over 50 percent of their training time is spent in a rural area.
- The number of FTE residents and the amount of time training in all 5 program years at both the urban and rural settings since establishment of a Rural Track Program (based on the rotation schedules), so that this information is available to the MAC when needed in auditing the accuracy of the RTP FTE cap limitation established by the hospital in the cost reporting period that coincides with or follows the start of the sixth program year of the RTP.

Following are examples of how the urban and rural hospital's rural track FTE limitations would be calculated:

Example 1: Urban Hospital and Rural Hospital are participating sites in an accredited rural track program. The program is in internal medicine (3 years minimum accredited length), and is accredited for a total of 6 residents, 2 in each program year (PGY). The residents spend PGY1 at Urban Hospital, and then the PGY2s and PGY3s rotate to a rural area, to train at both Rural Hospital and Rural Clinic (a nonprovider site). The PGY2 and PGY3 residents, while mostly assigned to the rural area, do come back to the Urban Hospital for some required training. However, the residents spend more than 50 percent of the duration of the 3 year program in the rural area. Therefore, the Urban Hospital qualifies to receive a cap/rural track FTE limitation adjustment. Rural Hospital incurs the cost of the salaries and fringe benefits of the residents for the time spent training at Rural Clinic and meets other applicable requirements at § 413.78(g) to be able to count the time residents spend training at the Rural Clinic. The rotations and the cap calculation are as follows:

Year 1	Year 2	Year 3	Year 4	Year 5
PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital.
PGY2 0	PGY2 2 @.90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20).	PGY2 2 @.90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20).	PGY2 2 @.90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20).	PGY2 2 @.90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20).
PGY3 0	PGY3 0	PGY3 2 @.95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10).	PGY3 2 @.95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10).	PGY3 2 @.95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10).
Total 2.0	TOTAL 4.0	TOTAL 6.0	TOTAL 6.0	TOTAL 6.0. 5 Year Total = 24.

Urban Hospital's 5 YEAR FTE TOTAL = 11.1

Rural Hospital's 5 YEAR FTE TOTAL (includes time at Rural Clinic) = 12.9

5 Year FTE Total = 24

Step 1: Highest number of FTE residents training in any program year during fifth year across all participating hospitals is 2.0:

PGY 1s = 2.0

PGY 2s = 2.0

PGY 3s = 2.0

Step 2: 2.0×3 (minimum accredited length) = 6.

Step 3: Urban Hospital's cap adjustment is based on the ratio of training at Urban Hospital over all 5 years to the total training that is occurring at all sites over all 5 years: $6 \times [11.1/(24)] = 2.76$.

Step 4: Rural Hospital's cap adjustment is based on the ratio of training at Rural Hospital and Rural Clinic over all 5 years to the total training that is occurring at all sites over all 5 years: $6 \times [12.9/(24)] = 3.24$.

$2.76 + 3.24 = 6.0$, the total cap assignment does not exceed the total number of accredited slots. Urban Hospital's rural track FTE limitation is 2.76. Rural Hospital's rural track FTE limitation is 3.24. (We note that this calculation is done separately for IME and direct GME caps respectively. Also note that during these 5 program years, the Urban Hospital and Rural Hospital exclude the FTE residents from the 3-year rolling average calculation on their Medicare cost reports.)

Example 2: Urban Hospital and Rural Hospital are participating sites in an accredited rural track program. The program is in psychiatry (4 years minimum accredited length), and is accredited for a total of 8 residents, 2 in each program year (PGY). The residents spend PGY1 at Urban Hospital, and then the PGY2s and PGY3s and PGY4s rotate to a rural area, to train at both Rural Hospital and Rural Clinic (a nonprovider site). The PGY2 and PGY3 and PGY4 residents, while mostly assigned to the rural area, do come back to the Urban Hospital for some required training. However, the residents spend more than 50 percent (that is, more than

24 months) of the duration of the 4 year program in the rural area. Rural Hospital incurs the cost of the salaries and fringe benefits of the residents for the time spent training at Rural Clinic and meets other applicable requirements at § 413.78(g) to be able to count the time residents spend training at the Rural Clinic. The rotations and the cap calculation are as follows:

Year 1	Year 2	Year 3	Year 4	Year 5
PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital.
PGY2 0	PGY2 2 @.90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20).	PGY2 2 @.90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20).	PGY2 2 @.90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20).	PGY2 2 @.90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20).
PGY3 0	PGY3 0	PGY3 2 @.95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10).	PGY3 2 @.95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10).	PGY3 2 @.95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10).
PGY4 0	PGY4 0	PGY4 0	PGY4 2 @.90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20).	PGY4 2 @.90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)
Total 2.0	TOTAL 4.0	TOTAL 6.0	TOTAL 8.0	TOTAL 8.0. 5 Year Total = 28.

Urban Hospital's 5 YEAR FTE TOTAL = 11.5

Rural Hospital's 5 YEAR FTE TOTAL (includes time at Rural Clinic) = 16.5

5 Year FTE Total = 28

Step 1: Highest number of FTE residents training in any program year during fifth year across all participating hospitals is 2.0:

PGY 1s = 2.0
PGY 2s = 2.0
PGY 3s = 2.0
PGY4s = 2.0

Step 2: 2.0 × 4 (minimum accredited length) = 8.

Step 3: Urban Hospital's cap adjustment is based on the ratio of training at Urban Hospital over all 5 years to the total training that is occurring at all sites over all 5 years: 8 × [11.5/(28)] = 3.29.

Step 4: Rural Hospital's cap adjustment is based on the ratio of training at Rural Hospital and Rural Clinic over all 5 years to the total training that is occurring at all sites over all 5 years: 8 × [16.5/(28)] = 4.71.

3.29 + 4.71 = 8.0, the total cap assignment does not exceed the total number of accredited slots. Urban Hospital's rural track FTE limitation is 3.29. Rural Hospital's FTE cap adjustment is 4.71. (We note that this calculation is done separately for IME and direct GME caps respectively. Also note that during these 5 program years, the Urban Hospital and Rural Hospital exclude the FTE residents from the 3-year rolling average calculation on their Medicare cost reports.)

Example 3: Refer to Example 1 (as previously described), where Urban Hospital and Rural Hospital are participating sites in an accredited internal medicine rural track program. The program is in internal medicine (3 years minimum accredited length), and is accredited for a total of 6 residents, 2 in each program year (PGY). Urban Hospital's rural track FTE limitation is 2.76. Rural Hospital's FTE cap adjustment is 3.24. In July 2023, Urban Hospital partners with Second Rural Hospital in a different rural part of the state to create another internal medicine RTT (that is, Urban Hospital internal medicine ''hub'' is adding another ''internal medicine RTT ''spoke''). Urban Hospital adds 2 FTE residents to train in PGY1 at the Urban Hospital, and then the PGY2s and PGY3s rotate to a rural area, to train at both Second Rural Hospital and Second Rural Clinic (a nonprovider site). The PGY2 and PGY3 residents, while mostly assigned to the rural area, do come back to the Urban Hospital for some required training. However, the residents spend more than 50 percent of the duration of the 3 year program in the rural area. Therefore, Urban Hospital qualifies to receive another rural track FTE limitation. Second Rural Hospital incurs the cost of the salaries and fringe benefits of the residents for the time spent training at Second Rural Clinic and meets other applicable requirements at § 413.78(g) to be able to count the time residents spend training at the Second Rural Clinic. The rotations and the cap calculation are as follows:

Year 1	Year 2	Year 3	Year 4	Year 5
PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital.
PGY2 0	PGY2 2 @.90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20).	PGY2 2 @.90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20).	PGY2 2 @.90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20).	PGY2 2 @.90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20).
PGY3 0	PGY3 0	PGY3 2 @.95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10).	PGY3 2 @.95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10).	PGY3 2 @.95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10).
Total 2.0	TOTAL 4.0	TOTAL 6.0	TOTAL 6.0	TOTAL 6.0. 5 Year Total = 24.

Urban Hospital's 5 YEAR FTE TOTAL = 11.1

Second Rural Hospital's 5 YEAR FTE TOTAL (includes time at Second Rural Clinic) = 12.9

5 Year FTE Total = 24

Step 1: Highest number of FTE residents training in any program year during fifth year across all participating hospitals is 2.0:

PGY 1s = 2.0
PGY 2s = 2.0
PGY 3s = 2.0

Step 2: 2.0 × 3 (minimum accredited length) = 6.

Step 3: Urban Hospital's cap adjustment is based on the ratio of training at Urban Hospital over all 5 years to the total training that is occurring at all sites over all 5 years: 6 × [11.1/(24)] = 2.76.

Step 4: [**Note:** As we explain in the summary of comments and responses, as a result of responding to one comment, we realized that the original Step 4 as included in the proposed rule contained errors. Therefore, we are replacing the language of Step 4 of the proposed rule with the following corrected language in this final rule with comment period]. Second Rural Hospital's cap adjustment is based on

the ratio of training at Rural Hospital and Rural Clinic over all 5 years to the total training that is occurring at all sites over all 5 years: 6 × [12.9/(24)] = 3.24 2.76 + 3.24 = 6.0, the total cap assignment does not exceed the total number of accredited slots. Urban Hospital's rural track FTE limitation is 2.76. *This second rural track FTE limitation is added to Urban Hospital's first rural track FTE limitation for a total rural track FTE limitation of 5.52 (2.76 + 2.76).* Second Rural Hospital's FTE cap adjustment is 3.24 (we note that Second Rural Hospital does not have a previous RTP FTE limitation). (We note that this calculation is done separately for IME and direct GME caps respectively. Also note that during these 5 program years, the hospitals exclude the FTE residents from the 3-year rolling average calculation *and the cap on the IME IRB ratio* on their Medicare cost reports.)

We invited comments on our proposals. Following is a summary of the comments received and our responses to those comments.

Comment: Commenters were overall very pleased with CMS's proposed implementation of section 127 of the CAA, and believe it addresses the teaching concerns of rural hospitals in a significant way. However, the commenters disputed CMS's concern that allowing expansion of existing programs might render RTT cap limitations meaningless. Commenters argued that nothing in section 127 of the CAA precludes CMS from providing a one-time adjustment opportunity to existing rural RTT spokes (rural providers). Commenters noted that CMS states in the IPPS proposed rule, ''Because the law now states 'established or establishes,' *both past tense and future tense,* we believe the statute grants the Secretary unique authority not previously held; that is, the authority to *prospectively* allow (under certain circumstances) cap adjustments to *existing RTTs expanded in a cost reporting period beginning on or after October 1, 2022*'' (emphasis added; 86 FR 25513). Many commenters urged CMS to create an exceptions process that would allow hospitals with existing RTTs to demonstrate that the only way they could train more residents at a rural hospital was to expand an existing RTT. They suggested that CMS could consider making this a one-time exception per program and limit the total number of residents allowed to 3.0 FTEs per program.

Response: We appreciate the commenters' support for our proposals. However, we disagree with how the commenters are interpreting ''established or establishes.'' We do not believe the past tense includes general expansions of existing programs. Rather, for the first time, the law allows adding additional sites to an already ''established'' RTP. As we stated in the proposed rule, ''. . . the provision gives explicit permission to adjust the RTT limitations of an urban hospital wishing to create additional RTTs *after establishing its first RTT,* while also adjusting the resident caps of the additional rural hospital(s) added by creating the second (or third, etc.) RTT . . . Therefore, under the explicit authority under section 127 of the CAA, we are proposing to prospectively allow increases to the IME and direct GME caps of both the participating urban and rural hospitals that *expand a qualifying RTT.* We are proposing that if, in a cost reporting period beginning on or after October 1, 2022, an urban hospital with an existing RTT (''hub' '') adds an additional RTT (''spoke'') to the existing urban core program of the same specialty, the urban and rural hospitals may receive adjustments to their rural track FTE limitation'' (86 FR 25513). That is, the new authority not previously available allows for an expansion of an existing, already ''established'' RTT by adding *additional participating sites* (not previously allowed). Section 127 of the CAA does not delineate an exceptions process as requested by commenters, even if an exception is limited to 3 FTEs or some other relatively small number. In the absence of such a delineation, we will not permit exceptions in some cases, but deny them in other cases. We interpret the clause in section 127 that the Secretary's rules shall be ''consistent with the principles of subparagraph (F)'' as a demonstration of Congressional intent to retain the FTE caps. Furthermore, this interpretation is consistent with our past interpretations of the principles of subparagraph (F), under which we have not permitted the addition of residents to an already existing program, whether at an urban or a rural hospital (see for example, May 12, 1998 (63 FR 26328, 26334, and 26335). Accordingly, we believe that allowing an exceptions process for expansions of RTPs at existing rural participating sites is inconsistent with our longstanding interpretations of subparagraph (F), and would render the FTE caps meaningless.

Comment: Numerous commenters provided feedback on the terminology CMS used in the proposed rule to describe different constructs of rural training and the manner in which they are accredited. For example, several commenters noted that CMS uses multiple terms to refer to possibly the same concept regarding ''rural training track,'' or ''rural training track program.'' The commenters recommend that CMS be careful in using these terms interchangeably, and define each separately, if they have a distinctive meaning for CMS. A commenter suggested that CMS clarify the difference between a separately accredited program and a track within a program that is already accredited, as follows:

- Separately accredited rural track *programs* (traditional 'RTTs' or integrated rural tracks as described in the FY2003 Final Rule; or 'RTPs,' Rural Track Programs in the new ACGME language just published in May 2021. (See *https://acgme.org/What-We-Do/Accreditation/Medically-Underserved-Areas-and-Populations/*)
- Urban programs with not-separately-accredited rural *tracks* ('RTs,' *not* programs)
- We consider 'tracks' of urban programs that do not place residents for training in rural locations for >50 percent of their training time to be '*pathways.*'

Response: We appreciate the comments encouraging consistent terminology, and we agree that in this final rule with comment period, we can improve the clarity and consistency in the language and the terms we used to describe programs in which residents rotate to rural areas. As pointed out in the comments, historically we have referred to the separately accredited family medicine programs which were eligible for the FTE cap adjustments under the BBRA of 1999 as ''Rural Training Tracks'' (RTTs), or ''Rural Training Track Programs.'' (See 65 FR 47026, 47033 through 47037 August 1, 2000) and the FY 2002 IPPS final rule (66 FR 39828, 39902 through 39909) and (68 FR 45456 through 45457 August 1, 2003). However, section 127 of the CAA shifts eligibility for FTE cap adjustments away from ''separate accreditation'' to an ''accredited program where greater than 50 percent of the program occurs in a rural area.'' Accordingly, going forward, so long as the training is not an expansion of an existing site's program, CMS' and the MACs' focus for determining an urban and rural hospital's eligibility for FTE cap adjustments is documentation showing that specific residents actually spend greater than 50 percent of the duration of their training in the program in a geographically rural area. CMS and the MACs will no longer look for evidence of ''separate accreditation''. We have spoken with the ACGME and we have

reviewed the terminology on the ACGME's website, and we intend to use the terminology ''Rural Track Program'' (RTP) in this final rule with comment period to describe the type of program that could qualify for IME and direct GME FTE cap adjustments. Specifically, at *https://acgme.org/What-We-Do/Accreditation/Medically-Underserved-Areas-and-Populations/,* the ACGME defines Rural Track Program (RTP) as follows: ACGME Rural Track Program (RTP)—An ACGME-accredited program with a unique 10-digit identifier in which residents/fellows gain both urban and rural experience with more than half of the education and training for each resident/fellow taking place in a rural area (any area outside of a Core-Based Statistical Area (CBSA)).

This definition of RTP includes the key point that the residents (or fellows, if applicable) spend more than half of their training in a geographically rural area. However, this current definition contains two points that CMS and the MACs will *not* require: (1) A unique 10-digit identifier, which we understand is characteristic of the separately accredited 1–2 programs, and (2) that ''each'' resident/fellow spends more than half of the education and training in a rural area. Our understanding is that, while it is certainly possible for a program to be designed such that ''each'' resident in the program is designated to spend more than 50 percent of the time in the rural area, it is also common for only a subset of residents within an entire accredited program to be designated for the rural training experience. Therefore, if only a subset of the number of residents for which a program is accredited is slated for the RTP, then, based on rotation schedules, the MAC would verify those residents and that their training experience consists of greater than 50 percent of the time in a rural area, and would calculate the FTE cap adjustment based on that proportion of FTEs spending more than 50 percent of their time in the rural area. Nevertheless, as stated previously, we are using the term RTP to refer to programs that, at least for a subset of the residents, meet the statutory requirement for greater than 50 percent of the training occurring in a rural area, and therefore, the urban and rural hospital could qualify for IME and direct GME rural track FTE limitations.

We are adding a new definition to the regulations at 42 CFR 413.75(b) for *Rural Track Program* as follows: ''*Rural Track Program* means, effective for cost reporting periods beginning on or after October 1, 2022, an ACGME-accredited program in which all, or some, residents/fellows gain both urban and rural experience with more than half of the education and training for the applicable resident(s)/fellow(s) taking place in a rural area as defined at 42 CFR 412.62(f)(iii). In the finalized regulations text at 42 CFR 412.105(f)(1)(v) and (x) and 42 CFR 413.79(k), effective for a cost reporting period beginning on or after October 1, 2022, if those programs (either the whole program, or a subset of residents in the program) consist of greater than 50 percent of the training time in a rural area, we will use the term ''Rural Track Program''. Conversely, in the same regulations text, when referring to programs where less than 50 percent of the training occurs in a rural area, we will use the term ''program,'' with no mention of ''rural''.

Comment: A commenter was concerned that in the absence of distinct ACGME criteria identifying programs where greater than 50 percent of the training occurs in a rural area, CMS should devise concrete criteria for identifying programs eligible for FTE cap adjustments. The commenter recommended that CMS require that a new 'director' be named in supporting materials for any newly created RTP but allow the program's 'director' to be any of the following in ACGME terms: A 'Program Director,' an 'Associate Program Director,' or even a participating 'site director' of a rural track that is not separately accredited. The same commenter requested that CMS define a not separately accredited rural track as ''an organized and deliberate urban residency program strategy to produce physicians to rural practice as indicated by all the following:

- A name for the rural track
- A director;
- A program-specific goal or objective(s) to recruit, nurture, educate, train, or encourage residents toward rural practice, including a separate NRMP number or another process for assigning individual residents to this track early in the first program year; and
- A description that explicitly articulates a rural focus, including a rotation schedule that demonstrates how the track will meet the 50 percent threshold for assigned residents training in a rural location.''

Response: In order to provide maximum flexibility to stakeholders, we believe it is appropriate for us to adhere to the criteria specified in section 127 of the CAA, rather than impose additional regulatory conditions for payment. We expect ACGME to develop additional criteria, which we believe is likely to occur in the coming years, as both the industry and the ACGME gain more experience with operating RTPs in a variety of specialties. Therefore, we are not adopting the commenter's suggested criteria.

Comment: A commenter requested that CMS confirm that as long as the residency program in its entirety is accredited by ACGME, there is no separate accreditation requirement or designation or recognition for the program to qualify as an RTT, above and beyond what is required under Medicare regulations. The commenter also requested that CMS confirm how it intends to treat RTTs that become immediately eligible as of October 1, 2022, due to meeting all regulatory requirements with the exception of the ''separate accreditation'' requirement.

Response: As we stated in response to the previous comment, we would use the ACGME's term ''Rural Track Program'' to refer to programs that are ACGME-accredited in their entirety, and where residents (either all, or a subset) spend greater than 50 percent of their training in the program in a rural area. We also do not understand why special consideration is needed for programs that become eligible for payment as an RTP immediately on October 1, 2022. As we stated, a hospital that believes it qualifies for an RTP FTE limitation should approach its MAC showing it meets the greater than 50 percent rural training requirement, and the MAC may adjust the hospital's interim rates so that effective for a cost report starting on or after October 1, 2022, the hospital could receive increased IME and direct GME payment as appropriate.

Comment: Some other commenters recommended using ACGME terms like ''participating hospital'' and to avoid the term ''sponsor''. The commenters noted that many, if not most, residency programs involve multiple participating hospitals and both provider and non-provider ambulatory sites, and that the sponsoring institution may not necessarily be a hospital. Some commenters also noted that in the Examples 1 and 2 on pages 25516–18 of the proposed rule, CMS refers to hospitals that ''jointly sponsor'' programs. The commenters noted that the ACGME does not use the term ''joint sponsor,'' and instead refers to hospitals as ''participating sites'' in an accredited program. In Example 3, a commenter corrected CMS's wording to indicate that Urban Hospital partners with Second Urban Hospital in a different part of the State to ''create'', and not to ''sponsor,'' another internal medicine RTT. A commenter also noted that the ACGME only allows one organization to serve as the Sponsoring Institution of an ACGME-accredited program, and that

education and training in each accredited program takes place in participating sites. A couple of other commenters noted that use of the term ''core'' and ''hub'' for the urban hospital are unnecessarily urban-centric, and suggest that the language be changed instead to 'networks' of multiple participating urban and rural hospitals and ambulatory sites.

Response: We appreciate the commenters' corrections and have made the suggested corrections in Examples 1, 2, and 3. We have consulted the ACGME's ''Glossary of Terms,'' dated April 15, 2020 (*https://www.acgme.org/portals/0/pdfs/ab_acgmeglossary.pdf*). After considering the commenters' suggestions, we believe it is best to use terms that are already defined in the ACGME's Glossary. We found the following relevant definitions:

- *Primary clinical site:* The primary facility designated for clinical instruction in the program.
- *Participating site:* An organization providing educational experiences or educational assignments/rotations for residents/fellows. Examples of participating sites include: A university; a medical school; a teaching hospital, including its ambulatory clinics and related facilities; a private medical practice or group practice; a nursing home; a school of public health; a health department; a federally qualified health center; a public health agency; an organized health care delivery system; a health maintenance organization (HMO); a medical examiner's office; a consortium; or an educational foundation.

Accordingly, in this final rule with comment period and going forward, rather than refer to the ''core'' and ''hub'' for the urban hospital, and ''spoke'' for the rural training sites, in this final rule with comment period, we instead will refer to the urban hospital(s) as the ''primary clinical site,'' and will refer to the various other training locations as either the ''rural hospital participating site,'' if the site is a rural hospital, or the ''rural non-provider participating site'' if the site is an ambulatory clinic, or some other non-hospital site. For illustrative purposes, had we used this new terminology in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25515), we would have written the language as follows:

We are proposing that if, in a cost reporting period beginning on or after October 1, 2022, an urban hospital with an existing ~~RTT~~ RTP (''primary clinical site'') adds an additional ~~RTT~~ ~~(''spoke'')~~ rural ''participating site'' to the existing urban ~~core program~~ RTP of the same specialty, the urban and rural hospitals may receive adjustments to their rural track FTE limitation. ~~(For ease of reference, we are referring to the urban core hospital as the 'hub'' and the one or more RTTs as the ''spokes'' associated with that urban ''hub.'~~ For example, Urban Hospital A (primary clinical site) has an existing family medicine program. In 2015, Urban Hospital A partnered with Rural Hospital 1 (rural hospital participating site) to create a ~~RTT~~ RTP from the existing family medicine program and received a rural track FTE limitation to reflect the time that residents training in the ~~RTT~~ RTP spent at its facility. In July 2023, Urban Hospital A (primary clinical site) partners with Rural Hospital 2 (an additional rural hospital participating site) in a different rural area of the State, to create an additional family medicine ~~RTT~~ RTP ~~(adding another ''spoke'' to the existing urban program ''hub.'')~~ We are proposing that both Urban Hospital A and Rural Hospital 2 may receive adjustments to their resident caps (rural track FTE limitations) to reflect the portion of the time that FTE residents in the second ~~family medicine RTT ''spoke''~~ rural hospital participating site RTP spend at their respective facility.

Comment: A commenter reviewed our proposed reiterated criteria for hospitals to seek MAC approval to receive payment for RTPs (see 86 FR 25516), and made the following suggested edits:

1. ~~The accreditation for the ''spoke,~~ ''Approval of the urban program's rural track from the ACGME and information whether the track is in the same specialty as an RTT/RTP program that the urban hospital already has, or whether the ''~~spoke''~~ track is a newly created ~~RTT~~ rural track in a different specialty.

2. Intern and resident rotation schedules (or similar documentation) showing that residents in ~~each particular RTT program (both hub and spokes overall)~~ the specified rural track spend greater than 50 percent of their training in the initial residency period in a geographically rural area in order to receive IME and direct GME rural track FTE limitations.

3. The number of FTE residents and the amount of time training in all program years at both the urban and rural settings since establishment ~~of the particular ''spoke~~ of any already accredited RTT/RTP or approved not-separately-accredited RT, so that the MAC may be able to verify the RTT cap and appropriately adjust the rural FTE limitation.

Response: We appreciate the commenter's suggestions, and will revise the criteria as follows:

- The ACGME accreditation for the program as a whole (that is, both urban and rural training components), and documents showing whether the urban and rural participating sites are creating the RTP for the first time in this particular specialty, or whether the urban and rural hospital already have an RTP in this specialty, but are adding additional participating sites to the RTP.
- Intern and resident rotation schedules (or similar documentation) showing that residents in the specified RTP spend greater than 50 percent of their training in a geographically rural area in the 5-year growth window order to receive IME and direct GME rural track FTE limitations. In the instance where only a subset of the residents in the particular program are participating in the RTP, and the training time of the RTP residents is included in the main rotation schedule for the entire program, the hospital must specifically highlight the names of the residents on the main rotation schedule, and highlight their urban and rural training locations, so that the MAC can easily identify which residents are training in the RTP, and be able to verify that over 50 percent of their training time is spent in a rural area.
- The number of FTE residents and the amount of time training in all 5 program years at both the urban and rural settings since establishment of a Rural Track Program (based on the rotation schedules), so that this information is available to the MAC when needed in auditing the accuracy of the RTP FTE cap limitation established by the hospital in the cost reporting period that coincides with or follows the start of the sixth program year of the RTP.

We note that under the second bullet, we removed the phrase ''in the initial residency period'' and changed it to ''in the 5-year growth window'' because we believe that is what the commenter intended to say (we note the phrase ''initial residency period'' as defined at 42 CFR 413.79(a) does not make sense in this context).

Comment: A commenter requested that CMS confirm that a hospital that is physically located in an urban area but treated as rural for purposes of payment under the IPPS as implemented in § 412.103 would be considered urban for purposes of meeting the requirements for the RTT provision and would be eligible for both DGME and IME cap adjustments as an urban hospital should it successfully partner with a hospital physically located in a rural area.

Response: Hospitals physically located in urban areas, but that are

reclassified to rural areas under 42 CFR 412.103 are treated as rural for IPPS payment purposes, which includes IME. This is because 42 CFR 412.103 affects payments under section 1886(d) of the Act, which are the IPPS payments, and IME is an add-on to the teaching hospital's IPPS payment. However, 42 CFR 412.103 does *not* affect direct GME because direct GME is addressed under section 1886(h) of the Act. This means that such a hospital is rural for IME purposes, but it is urban for direct GME purposes (because it is still physically located in an urban area). Therefore, we are not confirming the commenter's statement that the urban hospital reclassified as rural under 42 CFR 412.103 would be considered urban for the purpose of meeting the RTP requirements. Rather, the hospital would be rural for IME and urban only for direct GME. We did not propose any changes to this policy. Thus, as long as an urban hospital retains its 412.103 reclassification, CMS would treat that hospital as rural for section 1886(d) purposes, which includes all ramifications to the IME adjustment.

With regard to urban hospitals that are reclassified as rural under § 412.103 and participate in RTPs, there are challenges associated with correctly determining the payment implications for an RTP that has, as its primary clinical site, or even as a participating site, a hospital that is rural for IME purposes, but is urban for direct GME purposes. For instance, in determining whether greater than 50 percent of residents' training time occurs in an urban area or a rural area, would the training that occurs in this hospital that is rural for IME but urban for direct GME be counted towards the urban portion or the rural portion? The answer is that for the purpose of qualifying for an adjustment to only the IME FTE limitation, the residents' training time spent in the urban hospital reclassified as rural under 42 CFR 412.103 could count toward the rural portion of training time. However, the hospital would be in the awkward position of needing to send those same residents to train in a geographically rural participating site in order to separately meet the greater than 50 percent rural training requirement to qualify for the adjustment to the direct GME FTE limitation. Urban hospitals reclassified as rural under 42 CFR 412.103 that wish to participate in RTPs may decide that it is preferable both from an educational and economic standpoint to synchronize the time spent in geographically rural participating sites, so that the IME and direct GME rotations would be synchronized as well. It would also be much easier to document the training time to the MAC for the purpose of receiving the IME and direct GME FTE limitation adjustment.

Comment: A commenter noted that in the proposed rule, we stated that ''as with the general FTE resident caps, since the slots associated with the RTT FTE limitation are fungible, urban and rural hospitals with multiple RTT ''spokes'' may reduce the number of FTE residents training at one track and ''spoke'' in order to accommodate an increase in training and funding at another track and ''spoke'' (86 FR 25514). The commenter requested clarification on how the ''fungible'' aspect would work in the following example: Urban Hospital A and Rural Hospital 1 decide to adjust the RTT limitation partnership between the two hospitals by adding additional family medicine residents and reducing the number of internal medicine residents. The commenter requested confirmation that this single RTT cap limitation across two hospitals cross-training multiple specialties is what is intended by this example.

The commenter also requested confirmation regarding a second example demonstrating the fungible nature of the rural track FTE limitation. The commenter noted that CMS includes a more formal example (Example 3, 86 FR 25518) later in the preamble. In Example 3, which builds on Example 1, Urban Hospital forms a second rural training track in internal medicine with ''Second Rural Hospital.'' According to Example 3, Urban Hospital's first rural track FTE limitation and second rural track FTE limitation are added together to form a single rural track FTE limitation *for that particular specialty* (internal medicine). CMS includes a note that the ''*second rural track FTE limitation is added to Second Rural Hospital's first rural track FTE limitation for a total rural track FTE limitation of 6.48 (3.24 + 3.24)*'' (emphasis by CMS; 86 FR 25519). However, there is no indication in the earlier part of Example 3 of the origin of Second Rural Hospital's first rural track FTE limitation, and in particular whether it came from the same specialty or a different specialty. The commenter believed the intent is to demonstrate that Second Rural Hospital's first rural track FTE limitation was in a different specialty (not internal medicine), and the two distinct specialty rural track FTE limitations get added together to, again, form a single RTT cap limitation that was created via multiple specialties. The commenter requested confirmation that this single RTT cap limitation for Second Rural Hospital across multiple specialties is what is intended by this example.

Response: Regarding the first example, we partially confirm the commenter's general understanding, that if Urban Hospital A and Rural Hospital 1 receive RTP cap limitations for both family medicine and internal medicine, the two FTE cap limitations calculated as a result of each respective specialty may be added for a total RTP cap limitation *at each respective hospital, not across both hospitals.* Then, within each respective hospital's total RTP FTE cap limitation, the actual number of residents in each RTP may be reduced in one specialty, and increased in another specialty. For example, if a hospital has a total RTP FTE cap limitation of 6, consisting of 3 from a family medicine RTP, and 3 from an internal medicine RTP, the hospital could choose to reduce the family medicine RTP to 2 FTEs, and increase the internal medicine RTP to 4 FTEs, while still staying within the total RTP FTE cap limitation of 6. However, we disagree with the commenter's belief that a ''single RTT cap limitation across two hospitals cross-training multiple specialties'' is permissible. There is no ''single RTP cap limitation across two hospitals.'' Rather, each hospital, whether urban or rural, has its own IME and direct GME RTP FTE limitations; we are not creating Medicare GME affiliation agreements specific to sharing RTP FTE limitations. We note that, as with regular FTE caps, hospitals are free to increase or decrease FTE residents in any specialty at any location, but Medicare would only pay each hospital for no more FTEs than the amount in their RTP FTE limitations.

Regarding the commenter's second request for confirmation referencing Example 3 on page 25518 and 25519 of the proposed rule, we have reviewed this Example 3, and realize that we made an error. As the commenter notes, Example 3 does build on Example 1. Urban Hospital forms a *second* rural track FTE limitation in internal medicine with ''Second Rural Hospital.'' According to Example 3, Step 4, Urban Hospital's first rural track FTE limitation and second rural track FTE limitation are added together to form a single rural track FTE limitation *for that particular specialty* (internal medicine). CMS includes a note that the ''*second rural track FTE limitation is added to Second Rural Hospital's first rural track FTE limitation for a total rural track FTE limitation of 6.48 (3.24 + 3.24)*'' (emphasis by CMS; 86 FR 25519). However, that is incorrect, because Second Rural Hospital *had no previous*

rural track FTE limitation (it was First Rural Hospital in Example 1 that already had a rural track FTE limitation of 3.24, but First Rural Hospital is NOT part of Example 3; rather, Second Rural Hospital is at issue, and in fact is just receiving a rural track FTE limitation of only 3.24 for the first time). It is Urban Hospital that, under Example 3, has two rural track FTE limitations which are added together to form a total rural track FTE limitation for Urban Hospital of 5.52 (2.76 + 2.76). The intent of this Example 3 was to show how the limitations are calculated when ''Urban Hospital internal medicine ''hub'' adds another ''internal medicine RTT 'spoke' '' ((86 FR 25518) or, in terms used in this final rule with comment period, urban primary clinical site added a second rural hospital participating site but for the same specialty program). We are rewriting Step 4 of Example 3 in this final rule with comment period as follows:

Step 4: Second Rural Hospital's cap adjustment is based on the ratio of training at Rural Hospital and Rural Clinic over all 5 years to the total training that is occurring at all sites over all 5 years: $6 \times [12.9/(24)] = 3.24$. 2.76 + 3.24 = 6.0; therefore, the total cap assignment does not exceed the total number of accredited slots. Urban Hospital's rural track FTE limitation is 2.76. *This second rural track FTE limitation is added to Urban Hospital's first rural track FTE limitation for a total rural track FTE limitation of 5.52 (2.76 + 2.76).* Second Rural Hospital's FTE cap adjustment is 3.24 (we note that Second Rural Hospital does not have a previous RTP FTE limitation). We note that this calculation is done separately for IME and direct GME caps respectively per 42 CFR 412.105(f)(1)(x) for IME and 42 CFR 413.79(k) for direct GME. Also note that during these 5 program years, the hospitals exclude the FTE residents from the 3-year rolling average calculation *and the cap on the IME IRB ratio* on their Medicare cost reports.

At this point, Urban Hospital has a RTP FTE limitation of 5.52, while First Rural Hospital from Example 1 has a RTP FTE limitation of 4.71, and Second Rural Hospital from revised Example 3 has a RTP FTE limitation of 3.24. Each hospital's RTP FTE limitations for IME and direct GME respectively belong to each hospital, and are derived from a single specialty, internal medicine. Thus, there are not yet any slots to be fungible. The slots can be fungible when there is more than one specialty RTP. We can elaborate on Example 3 further, and imagine that Urban Hospital and First Rural Hospital decide to create a new RTP in pediatrics. Five years pass, and both Urban Hospital and First Rural Hospital receive RTP FTE limitations associated with the pediatrics RTP, and that Urban Hospital's RTP FTE limitation has increased from 5.52 to 8.0, and First Rural Hospital's RTP FTE limitation increased from 3.24 to 6.0. After some more time, Urban Hospital and First Rural Hospital believe there is a need to expand their complement of residents training in their existing internal medicine RTP. However, since adjustments to RTP FTE limitations are not provided for expansions of existing programs, they decide to reduce the complement of pediatrics residents by 1.0, and increase the complement of internal medicine residents training in the RTP at Urban Hospital and First Rural Hospital by 1.0. Thus, both Urban Hospital and First Rural Hospital maintain training levels *within* their respective existing RTP FTE limitations. This demonstrates the fungible nature of each hospital's RTP FTE limitations, when there is more than one RTP specialty.

Comment: A commenter requested that CMS comment on the following example. Urban Hospital A has an internal medicine RTT with two rural hospitals (Rural Hospital X and Rural Hospital Y). Urban Hospital A has an internal medicine RTT limitation of 5.0, which was established by expanding its internal medicine program by 15 rural track residents, training 5.0 FTE residents in Urban Hospital A and rotating 5.0 FTE residents to Rural Hospital X and 5.0 FTE residents to Rural Hospital Y. After the RTT cap for the program was established, Urban Hospital A decides to rotate more residents to Rural Hospital X (increase to 6.0) and fewer residents to Rural Hospital Y (decrease to 4.0). Rural Hospital X would be training above its internal medicine RTT limitation. Rural Hospital Y would be training below its internal medicine RTT limitation. The commenter believed that Urban Hospital A would retain its internal medicine RTT limitation of 5.0, even if the number of residents training in Rural Hospital X and Rural Hospital Y changed. The commenter also believed that Rural Hospital X and Rural Hospital Y could form an affiliated group and aggregate their FTE caps such that Rural Hospital X raises its FTE cap by 1.0 and Rural Hospital Y lowers its FTE cap by 1.0 to accommodate Urban Hospital A's rotation change. The commenter requested confirmation that an urban hospital's RTT cap limitation for a single specialty would not change, even if its spokes altered the amount of training occurring at each spoke hospital, and that the spoke hospitals may form a Medicare affiliated group agreement to share rural track FTE limitation ''space.''

Response: In the situation where the FTEs at the Urban Hospital's portion of the RTP do not change, but there is a change at the Rural Hospitals, such that there is an increase of FTEs at one Rural Hospital with a decrease at another Rural Hospital, we agree that Urban Hospital's RTP FTE limitation and payment would not change, because it is still sending the same amount of FTEs to a rural area for greater than 50 percent of the program. However, payment to the Rural Hospitals would change. Rural Hospital X would be training in excess of its RTP FTE limitation, and would not be paid for the amount of FTEs in excess of its RTP FTE limitation. While Rural Hospital Y would now have ''room'' under its RTP FTE limitation, it would receive payment only for the number of FTEs in the RTP it trains. As we mentioned previously, effective October 1, 2022, we are not permitting the formation of Medicare GME affiliated groups for the purpose of aggregating and cross-training RTP FTE limitations. First, we believe Medicare GME affiliated groups for RTPs are premature at this point, as only starting October 1, 2022 would hospitals have the first opportunity to add additional participating sites. Subsequently, there would be the 5-year cap building period in which Medicare GME affiliations are not permitted, even under existing Medicare GME affiliation agreement rules (42 CFR 413.79(f)). Second, before we create Medicare GME affiliation agreements unique to RTPs, we believe it would be best to first modify the Medicare cost report form to add spaces for the hospitals to indicate the number of any additional RTP FTEs, and the caps applicable to those FTEs. We also wish to assess flexibility within a hospital's own total RTP FTE limitation, before sharing those slots with other hospitals. We would need to be vigilant to ensure that the RTP FTE limitations are not comingled with regular FTE cap adjustments currently used in Medicare GME affiliation agreements. Therefore, we believe it is best to reassess allowing Medicare GME affiliation agreements for RTP FTE limitations at some point in the future.

Comment: A commenter noted that CMS stated in the proposed rule that RTTs will be prospectively exempt from the rolling average ''for RTTs started in cost reporting periods beginning on or after October 1, 2022'' (86 FR 25515). Several commenters believe this effective date will adversely impact

many programs just developed with HRSA funding this past 2 years, and special consideration should be given for 7 programs expected to begin July 1, 2022. The commenters recommended that the effective date should be aligned with the start of the academic year, so that the rolling average should instead be ''effective for RTTs starting in Academic Year 2022–23 (July 1, 2022) and beginning with their cost reports starting on or after October 1, 2022. . . .'' Another commenter suggested that FTEs in RTTs be prorated such that the rolling average would not apply for portions of cost reporting periods on or after October 1, 2022.

Response: First, we acknowledge an error that we made in the proposed rule with regard to the effective date of the exemption from the rolling average. That is, a commenter noted that CMS stated in the proposed rule that RTTs will be prospectively exempt from the rolling average ''for RTTs *started in* cost reporting periods beginning on or after October 1, 2022'' (emphasis added, 86 FR 25515). In fact, section 127 of the CAA states ''for cost reporting periods beginning on or after October 1, 2022 . . .;'' the law does *not* state that for RTTs ''started in'' cost reporting periods beginning on or after October 1, 2022. This means that even for RTTs started *prior* to October 1, 2022, so long as the urban hospital and rural hospital are within the 5-year growth window for FTE residents participating in the RTT, the earliest a hospital can first benefit from the rolling average exemption is a hospital's first cost reporting period beginning on or after October 1, 2022. We also note that the law changes the heading at section 1886(h)(4)(H)(iv)(I) to be ''cost reporting periods beginning before October 1, 2022,''; the statutory effective date is explicit. We cannot allow hospitals to prorate and exclude FTEs from the rolling average for the portion of the cost reporting period that occurs after October 1, 2022, because the law does not say ''for portions of cost reporting periods on or after October 1, 2022.'' The law also does not specify that special consideration be given to programs with a start date of July 1, 2022. We understand any disappointment related to waiting for the rolling average exemption in the first cost reporting period starting on or after October 1, 2022, but we cannot alter this statutory effective date. Therefore, new programs started on July 1, 2022 would still be subject to the rolling average for the cost reporting period that started prior to October 1, 2022. Only effective with a hospital's cost reporting period starting on or after October 1, 2022 would the new rules regarding not needing separate accreditation for the RTT or exemption from the rolling average apply.

Comment: A commenter pointed out that CMS uses the authority within section 1886(d)(5)(B)(viii) of the Act, which specifies ''[r]ules similar to the rules of subsection (h)(4)(H) shall apply for purposes of clauses (v) and (vi)'' to exempt new teaching hospitals from being held to the IME intern and resident-to-bed (IRB) ratio cap during the cap-building period. Since section 1886(d)(5)(B)(vi)(I) is the part of the statute that imposes the IRB ratio cap, the commenter believes that CMS has authority under section 1886(d)(5)(B)(viii) to also grant an exemption to RTTs from the IRB ratio cap during their cap-building windows and should exercise its authority to do so.

Response: We agree that urban and rural hospitals within a 5-year cap building period for an RTP would not apply the IME IRB ratio cap during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each RTP. The commenter refers to section 1886(h)(4)(H) of the Act, called ''Special rules for application of subparagraphs (F) and (G).'' Subparagraph (F) is the FTE resident cap for direct GME, and subparagraph (G) refers to the 3-year rolling average for direct GME. Section 1886(h)(4)(H) provides the authority for CMS to exempt new teaching hospitals first establishing new programs from applying the FTE caps and the 3-year rolling average during the 5-year cap building period. Section 1886(h)(4)(H)(iv) provides the special authority for exemptions for RTPs. Similarly, on the IME side, section 1886(d)(5)(B)(viii) refers to subsection (h)(4)(H) in order to exempt new teaching hospitals first establishing new programs from applying the IME FTE cap (section 1886(d)(5)(B)(v)), the IME 3-year rolling average (section 1886(d)(5)(B)(vi)(I)), and the IME IRB ratio cap (section 1886(d)(5)(B)(vi)(II)). Thus, by specifying that rules similar to the rules of subsection 1886(h)(4)(H) shall apply, the statute exempts RTPs within their 5-year cap building period from application of the FTE caps, the 3-year rolling average for IME and direct GME, and effective for cost reporting periods beginning on or after October 1, 2022, the IRB ratio cap for IME as well.

Comment: A commenter expressed concern regarding the implementation of a new OMB definition of non-metropolitan (that is, 'rural' and 'not urban', (micropolitan = <100,000 population)), and how it may impact RTPs. The commenter suggested CMS outline a policy that covers RTPs and changes to CBSAs that inevitably occur every census from population change.

Response: Currently, CMS has made no proposals to adopt such OMB changes. If and when CMS does propose changes similar to those proposed by OMB, we would address their ramifications in proposed rulemaking at the appropriate time. In the meantime, we refer readers to existing policy regarding changes resulting from census data; see 42 CFR 413.79(k)(7), implemented in the August 22, 2014 IPPS final rule (79 FR 50111 through 50117).

Comment: Some commenters encouraged CMS to include RTT programs within consortium agreements with urban hospitals for inpatient rotations and FQHCs for outpatient clinics, as this would provide needed physicians for FQHCs with waiting lists of untreated patients, and would foster the training of primary care physicians.

Response: CMS does not have any specific rules regarding RTPs and inclusion or exclusion within consortium agreements, so we are unclear as to why CMS would need to do so now. To the extent that there are FQHCs located in rural areas, RTP training time spent in such FQHCs would be counted in the portion of the RTP that is in the rural area.

h. Final Policies and Changes to the Regulations Text

We are finalizing our proposed policies with minor adjustments but no substantive policy changes. We are also finalizing changes to the regulations text for IME at 42 CFR 412.105 to mirror regulations text changes for direct GME, and we are finalizing changes to the direct GME regulations as follows:

- We are adding a new definition of Rural Track Program at 42 CFR 413.75(b).
- We are finalizing the modification to the definition of Rural Track FTE limitation at 42 CFR 413.75(b) to add ''or rural hospital''.
- We removed the requirement at 42 CFR 413.79(d)(7) that FTE residents in the RTP are included in the 3-year rolling average during the 5-year cap building window, and at 42 CFR 412.105(a)(1)(i), we are stating that in cost reporting periods beginning on or after October 1, 2022, FTE residents in the RTP are exempt from the cap on the IRB ratio during the 5-year cap building window.
- We are finalizing various changes throughout the regulations text at 42

CFR 413.79(k) ''*Residents training in rural track programs.*''

5. Implementation of Section 131 of the CAA; Addressing Adjustment of Low Per Resident Amounts (Direct GME) and Low FTE Resident Caps (Direct GME and IME) for Certain Hospitals

Section 131 of the CAA provides us with the opportunity to reset the low or zero direct GME per resident amounts of certain hospitals, and to reset the low IME and direct GME FTE resident caps of certain hospitals. Regarding direct GME PRAs, section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period PRA that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). For hospitals that became teaching hospitals after 1984, section 1886(h)(2)(F) of the Act states that ''the Secretary shall, for the first such period for which it has such a residency training program and is participating under this title, provide for such approved FTE resident amount as the Secretary determines to be appropriate, based on approved FTE resident amounts for comparable programs.'' The regulations at 42 CFR 413.77(e)(1) implement this provision, stating that the per resident amount is based on the lower of the amount specified in paragraph (e)(1)(i) or paragraph (e)(1)(ii) of that section, subject to the provisions of paragraph (e)(1)(iii) of this section. In other words, the new teaching hospital's PRA generally will be based on the *lower of* its actual GME costs per FTE in its base period, or the weighted average PRA of existing teaching hospitals located in the same core-based statistical area (CBSA) as the new teaching hospital. Under section 1886(h)(2)(D) of the Act, once the PRA is established in a base period, no changes are made to it; it is only updated for inflation in each subsequent year.

The calculations of both direct GME payments and the IME payment adjustment are affected by the number of FTE residents that a hospital is allowed to count. Congress, through the Balanced Budget Act of 1997 (Pub. L. 105–33), established a limit on the number of allopathic and osteopathic residents that a hospital may include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied, effective for discharges occurring on or after October 1, 1997.

a. Background on Establishment of PRAs and FTE Resident Caps for Hospitals Hosting Residency Training

Section 1886(h)(2)(F) of the Act does not require a hospital to incur costs, be the program sponsor, or train a certain minimum number of FTE residents, in order to become a teaching hospital. Accordingly, under the regulations at 42 CFR 415.152, ''Teaching hospital'' is defined as a hospital engaged in an approved GME residency program in medicine, osteopathy, dentistry, or podiatry. Our historical policy is that if a hospital has residents that are training in an approved GME residency program(s), and if the training is according to a planned and regular schedule (that is, not spontaneous or random), then we consider the hospital to be a teaching hospital, even if—

- It is not incurring the costs of the residents' salaries and fringe benefits,
- It is not the sponsor of the program,
- It is only training a very small number of FTE residents, and
- The program in which the residents are training does not have to be a ''new'' program under Medicare rules.

As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25520), in the past, a number of hospitals have found themselves in the situation of establishment of a low PRA, when they served as a training site for only small numbers of residents from programs sponsored by a medical school or another hospital. In many cases, these hospitals did not incur any salaries for those residents and may have incurred only insignificant overhead costs associated with the residents' presence at their facilities and, therefore, their PRAs were either very low or $0. Such low PRAs preclude meaningful direct GME payment in the future if these hospitals expand their training of residents and incur significant costs associated with the training. Section 131(a) of the CAA amends section 1886(h)(2)(F) of the Act to direct the Secretary, for such hospitals with such extremely low or $0 PRAs that meet certain criteria, to establish new PRAs using the methodology described in 42 CFR 413.77(e) if the hospital trains resident(s) in a cost reporting period beginning on or after its enactment (December 27, 2020) and before the date that is 5 years after enactment (December 26, 2025). In accordance with 42 CFR 413.77(e), a new teaching hospital's PRA is based on the *lower of* its actual GME costs per FTE during a specific base year, or the weighted average PRA of existing teaching hospitals located in the same core-based statistical area (CBSA) as the new teaching hospital. Similar to the establishment of low PRAs, in the past, a number of hospitals have found themselves in the situation of establishing low (but greater than zero) direct GME and IME FTE caps when they served as training sites for only small numbers of residents. The statute does not require that a hospital train a certain minimum number of FTE residents in order to establish permanent caps. Hospitals wishing subsequently to participate in training residents in a significant manner were precluded by low FTE resident caps from receiving meaningful IME and direct GME payments. Section 131(b) of the CAA addresses this problem by amending section 1886(h)(4)(H)(i) to add new subclauses (III) and (IV) to direct the Secretary, for hospitals that meet certain criteria and that have very low FTE resident caps, to ''adjust''—that is, redetermine—those caps if the Secretary determines that the hospital begins training residents in a program year beginning on or after enactment (December 27, 2020) and before 5 years after enactment (December 26, 2025).

b. Hospitals Qualifying To Reset Their PRAs

Section 131(a) of the CAA also amends section 1886(h)(2)(F) of the Act to add a new clause (iii) to describe the categories of hospitals that qualify to receive a replacement PRA. For ease of reference, we will refer to these hospitals as Category A and Category B. As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25520), a Category A Hospital is one that, as of the date of enactment (December 27, 2020), has a PRA that was established based on less than 1.0 FTE in any cost reporting period beginning before October 1, 1997. Typically, a Category A hospital is one that trained less than 1.0 FTE in its most recent cost reporting period ending on or before December 31, 1996, and received a very low or $0 PRA. A Category B Hospital is one that, as of the date of enactment (December 27, 2020), has a PRA that was established based on training of no more than 3.0 FTEs in any cost reporting period beginning on or

after October 1, 1997, and before the date of enactment (December 27, 2020). This new subclause provides that the Secretary shall in lieu of these low PRAs, establish a new PRA in accordance with the process described in § 413.77(e), *for each such hospital if the hospital trains at least 1.0 FTE* (in the case of a Category A hospital) or *more than 3.0 FTEs* (in the case of a Category B hospital) (emphasis added). The recalculation period begins on December 27, 2020, and ends 5 years later.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25520 through 25521), we proposed that to redetermine the PRA, the training occurring at a Category A Hospital or a Category B Hospital need *not necessarily* be training residents in a *new* program; the residents may be in either an approved program that is ''new'' for Medicare IME and direct GME purposes, or may be in an existing approved program. This is because the new subclause does not state that the training be in a ''new'' program, and furthermore, CMS's current policy is that for a hospital which starts training residents for the first time, the PRA can be established based on the training of residents in either a ''new'' approved program, or an existing approved program. However, for a Category A Hospital, we proposed not to reset its PRA until we determine that the Category A Hospital trains at least 1.0 FTE, and that training must occur in a cost reporting period beginning on or after December 27, 2020 (date of enactment) and before December 26, 2025 (5 years after enactment). Similarly, for a Category B Hospital, we proposed not to reset its PRA until we determine that the Category B Hospital trains more than 3.0 FTEs, and that training must occur in a cost reporting period beginning on or after December 27, 2020 (date of enactment) and before December 26, 2025 (5 years after enactment). Because new section 1886(h)(2)(F)(iii) uses the word ''trains'', we interpret this to require ''continuous'' training, and therefore, we proposed that for both Category A and B Hospitals, it is not relevant whether they may have trained at least 1.0 FTE or more than 3.0 FTEs in a cost reporting period or periods prior to December 27, 2020. While we proposed that such previous training of at least 1.0 FTE or greater than 3.0 FTEs would not preclude resetting of a Category A Hospital's PRA or a Category B Hospital's PRA, we proposed that the relevant factor in determining when to reset their PRAs would be if and when the hospital trains the requisite amount of FTE residents in a cost reporting period beginning on or after December 27, 2020 (date of enactment) and 5 years after (December 26, 2025). For example, a Category A Hospital trains 6.05 FTEs in its cost reporting period beginning on January 1, 2020. The Category A Hospital trains 5.95 FTEs in its cost reporting period beginning on January 1, 2021. We proposed that we would reset this Category A Hospital's PRA effective with its cost reporting period beginning on January 1, 2021. In a second example, a Category B Hospital trains 6.05 FTEs in its cost reporting period beginning on January 1, 2020. The Category B Hospital trains 2.0 FTEs in its cost reporting period beginning on January 1, 2021. Then the Category B Hospital trains 3.25 FTE in its cost reporting period beginning on January 1, 2022. We proposed that we would reset this Category B Hospital's PRA effective with its cost reporting period beginning on January 1, 2022. Once reset, in the absence of additional legislation, the PRAs for either a Category A Hospital or a Category B Hospital are permanent, subject to annual inflation updates under 42 CFR 413.77(c)(1).

We refer readers to section II.B.5.f. of this final rule with comment period for a summary of the policies we are finalizing after consideration of public comments, on redetermination of PRAs provided under section 131 of the CAA.

c. Calculating the Replacement PRA and Cost Reporting Requirements

Consistent with the new statute, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25521), we proposed to calculate the replacement PRA using the existing regulations in place at 42 CFR 413.77(e). First, we proposed to use as the PRA base period the *first* cost reporting period beginning on or after December 27, 2020 in which either the Category A Hospital or Category B Hospital trains their requisite threshold FTEs; that is, at least 1.0 FTE is trained at Category A Hospital, and more than 3.0 FTEs are trained at Category B Hospital. Then, as 42 CFR 413.77(e)(1) states, we proposed to amend the regulations to add a new § 413.77(e)(1)(iv) to establish the replacement PRA as the LOWER OF—

- The hospital's actual cost per resident incurred in connection with the GME program(s) based on the cost and resident data from the hospital's replacement base year cost reporting period; and
- The updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area is calculated using all per resident amounts (including primary care and obstetrics and gynecology and nonprimary care) and FTE resident counts from the most recently settled cost reports of those teaching hospitals.
- If there are fewer than three existing teaching hospitals with per resident amounts that can be used to calculate the weighted mean value per resident amount, for base periods beginning on or after October 1, 1997, the per resident amount equals the updated weighted mean value of per resident amounts of all hospitals located in the same census region as that term is used in subpart D of part 412 of this subchapter.

We will issue instructions to the MACs and to hospitals to provide for an orderly process of request and review for the purpose of receiving replacement PRAs. When the hospital trained the requisite number of FTEs in a particular cost reporting period, upon submission of that cost report, the hospital will notify its MAC that it believes a replacement PRA can be determined. The MACs of the Category A and Category B Hospitals will review the GME costs and FTE counts reported in the Medicare cost report, rotation schedules supporting the FTE counts, etc. to determine at what point the requisite threshold of FTE residents are trained. As required under 42 CFR 413.20 and 413.24, hospitals must provide sufficient documentation to ensure proper payment (for GME, this includes, but is not limited to, rotation schedules and training agreements). We note that newly amended section 1886(h)(2)(F) of Act makes two points regarding cost reporting. First, clause 1886(h)(2)(F)(ii) states that in the case of a hospital that trains residents and has not entered into a GME affiliation agreement (as defined by the Secretary for purposes of paragraph (4)(H)(ii)), on or after the date of enactment of this clause, the Secretary shall not establish an FTE resident amount until such time as the Secretary determines that the hospital has trained as least 1.0 FTE resident in an approved medical residency training program in a cost reporting period. Medicare GME affiliation agreements, as implemented in the regulations at 42 CFR 413.79(f), permit teaching hospitals that cross train residents in the same programs to aggregate and share their FTE resident caps to facilitate movement of residents and reimbursement for that training. Entering into a Medicare GME affiliation agreement is a voluntary and conscious action on the part of a hospital. Therefore, even if a hospital trains less than 1.0 FTE (and this would be any hospital, not just a Category A Hospital or a Category B Hospital), but has entered into a Medicare GME affiliation

agreement for that training, we stated in the proposed rule that we believe the law is directing the Secretary to establish a PRA for that hospital. Thus, effective for a cost reporting period beginning on or after enactment (December 27, 2020), we proposed to establish a PRA in the instance where a hospital trains *less than 1.0 FTE* and that hospital has entered into a Medicare GME affiliation agreement for that training. However, in the instance where a hospital did *not* enter into a Medicare GME affiliation agreement for that training, we proposed to establish a PRA only when a hospital trains at least 1.0 FTE. We proposed to amend the regulations at 42 CFR 413.79(f) to reflect this new provision.

Second, section 1886(h)(2)(F)(iv) states that for purposes of carrying out this subparagraph for cost reporting periods beginning on or after the date of the enactment of this clause, a hospital shall report full-time equivalent residents on its cost report for a cost reporting period if the hospital trains at least 1.0 full-time equivalent resident in an approved medical resident training program or programs in such period. Accordingly, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25521 through 25522), we proposed that both a Category A Hospital and a Category B Hospital must accurately report FTEs on the IME Worksheet E, Part A and the direct GME Worksheet E–4 of CMS-Form-2552–10, when *either category of hospital* trains at least 1.0 FTE on or after December 27, 2020. We further proposed that *all* hospitals, even if they do not classify as Category A or Category B Hospitals, must enter the FTE counts on Worksheets E, Part A and E–4 of the CMS-Form-2552–10, for cost reporting periods during which the hospital trains at least 1.0 FTE. In addition, the hospital must provide the information required by the Interns and Residents Information System (IRIS) software for a cost report that contains at least 1.0 FTE on Worksheets E, Part A (IME) and E–4 (direct GME). We proposed this rule regardless of whether or not such hospital incurs the costs or is the program sponsor, because we believe that a PRA is established when a hospital trains at least 1.0 FTE (or, if there is a Medicare GME affiliation agreement, even less than 1.0 FTE). We proposed to amend the regulations at 42 CFR 413.78(b), with a cross-reference to 42 CFR 413.77(e) and 413.79(f), to require that effective for a cost reporting period beginning on or after December 27, 2020, a hospital must report FTE residents on its Medicare cost report for a cost reporting period if: (1) In the absence of a Medicare GME affiliation agreement, a hospital trains at least 1.0 FTE in an approved program or programs; or (2) if there is a Medicare GME affiliation agreement, a hospital trains less than 1.0 FTE in an approved program or programs. As we stated in the proposed rule, this proposed regulation would put hospitals on notice that they would establish a PRA when they report FTE residents on their Medicare cost report beginning on or after December 27, 2020.

On a technical note, newly added clause1886(h)(2)(F)(v) states that as appropriate, the Secretary may consider information from any cost reporting period necessary to establish a new FTE resident amount. Keeping in mind the regulations regarding predicate facts at 42 CFR 405.1885, our policy has been to refer, but not make changes, to a hospital's ''true'' base year under 42 CFR 413.77(e), even if that base year cost report is beyond the 3-year reopening rules. For example, if, in 2019, a MAC discovered that a hospital trained a small number of FTE residents in its 2005 cost reporting period, the MAC would use the 2005 cost report and documentation to obtain direct GME costs (if any, or $0) and the FTE resident(s), determine a cost per FTE, and compare that to the 2005 weighted average PRA of the other teaching hospitals in the same CBSA, even though the 2005 cost report was beyond the 3-year reopening period. In accordance with 42 CFR 413.77(e), the MAC would establish the LOWER of the two amounts to be the hospital's base year PRA. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25522), we proposed to continue to be consistent with our existing predicate fact regulations going forward, such that we would not reopen cost reports beyond their 3-year reopening period, but would refer to and use whatever contemporaneous documentation we would need to establish a PRA. However, because section 131 of the CAA directs the Secretary to replace a Category A Hospital's PRA or a Category B Hospital's PRA if the hospital trains at least 1.0 FTE or more than 3.0 FTEs in a cost reporting period beginning on or after such date of enactment and before the date that is 5 years after, we proposed to amend the regulations at 42 CFR 413.77(e) to use as the PRA base year for a Category A Hospital the cost reporting period beginning on or after December 27, 2020 and before December 26, 2025 in which that hospital trains at least 1.0 FTE, and for a Category B Hospital, the cost reporting period beginning on or after December 27, 2020 and before December 26, 2025 in which that hospital trains more than 3.0 FTEs. In determining whether a hospital trained the requisite thresholds of 1.0 or more than 3.0 FTEs, we proposed not to round up; that is, an FTE count of 0.99 would not be rounded up to be at least 1.00 FTE. Rather, the FTE count would have to equal at least 1.00 without rounding applied. Similarly, an FTE count would have to add to be greater than 3.00 without rounding rules applied.

d. Hospitals Qualifying To Reset Their FTE Resident Caps

Section 131(b) of the CAA 2021 amends section 1886(h)(4)(H)(i) of the Act to add new subclauses (II) through (V) to describe the categories of hospitals that qualify to receive a replacement PRA. For ease of reference, we continue to refer to these hospitals as Category A and Category B. As explained in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25522), a Category A Hospital is one that, as of the date of enactment (December 27, 2020), has an IME and/or direct GME FTE resident cap that was established based on less than 1.0 FTE in any cost reporting period beginning before October 1, 1997. Typically, a Category A hospital is one that did train less than 1.0 FTE in its most recent cost reporting period ending on or before December 31, 1996, and therefore, received FTE caps of less than 1.0 FTE (along with a very low or $0 PRA). A Category B Hospital is one that, as of the date of enactment (December 27, 2020), has an IME and/or direct GME FTE resident cap that was established based on training of no more than 3.0 FTEs in any cost reporting period beginning on or after October 1, 1997, and before the date of enactment (December 27, 2020). The new subparagraphs (III) and (IV) provide that the Secretary shall adjust the FTE resident cap in the manner applicable to a new approved medical residency training program, which under subparagraph (V), states that the adjustment to the FTE resident cap shall be made in a manner consistent with the methodology, as appropriate, in § 413.79(e). The Secretary shall adjust the FTE resident caps *if the hospital* ''*begins training*'' *at least 1.0 FTE* (in the case of Category A) or ''begins training'' *more than 3.0 FTEs (*in the case of Category B) in a *program year* beginning on or after such date of enactment and before the date that is 5 years after such date of enactment (emphases added).

Unlike our preceding proposal regarding resetting the PRAs of Category A and B Hospitals, where a training program does not necessarily need to be

new, in the case of resetting the FTE resident caps, we *did propose* that the FTE resident caps would only be reset when a Category A Hospital or Category B Hospital ''begins training'' FTE residents in a new residency program(s) (see our discussion of the definition of ''new program'' at 42 CFR 413.79(l) and 74 FR 43908 through 43917). Specifically, we emphasize that the new subparagraphs (III) and (IV) state that the Secretary shall adjust the FTE resident caps in the manner applicable to a new program if the Secretary determines the hospital ''*begins training*'' the requisite number of FTE residents (emphasis added). In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25522), we proposed that ''begins training'' means *future* training in a new program *for the first time on or after enactment.* We proposed that for both Category A and B Hospitals, it is not relevant whether they may have trained at least 1.0 FTE or more than 3.0 FTEs in a new program in a cost reporting period or periods prior to December 27, 2020; rather, we proposed that the relevant factor in determining the timing of resetting their FTE resident caps would be if the hospital *first begins training* the requisite amount of FTE residents at some point in a cost reporting period beginning on or after December 27, 2020 (date of enactment) and 5 years after (December 26, 2025). For example, a Category A Hospital trains 6.05 FTEs in a new program in its cost reporting period beginning on January 1, 2017. Category A Hospital trains 15.95 FTEs in its cost reporting period beginning on January 1, 2021. We proposed that we would NOT reset this Category A Hospital's FTE resident caps effective with its cost reporting period beginning on January 1, 2021, because it first began training residents in a new program *prior* to its cost reporting period beginning on or after enactment, and continued to train FTE residents in the new program after enactment. Rather, in order to qualify for a replacement FTE resident cap, both a Category A Hospital and a Category B Hospital would have to wait to start training residents in a new program in a cost reporting period beginning on or after enactment; if they started training residents in a new program at some point *prior* to enactment, we proposed that they would not qualify to receive replacement FTE resident caps. For example, a Category A Hospital wanted to start training residents in a new program, but delayed doing so because it believed it could not support a new residency program with IME and direct GME FTE resident caps of less than 1.0. With the enactment of section 131 of the CAA, this Category A Hospital receives accreditation to start a new residency program, and begins to train at least 1.0 FTE resident in the new program on July 1, 2022. We proposed to replace the small FTE resident caps of this Category A Hospital with new FTE resident caps in accordance with the regulations for calculating FTE resident caps for new programs at 42 CFR 413.79(e). We proposed to apply the same policy for a Category B Hospital that waits to train more than 3.0 FTE residents in a new program in a cost reporting period on or after December 27, 2020.

e. Calculating the Replacement FTE Resident Caps and Cost Reporting Requirements

Consistent with the new statutory provisions, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25523), we proposed to calculate the replacement FTE resident caps using the existing regulations in place at 42 CFR 413.79(e)(1). First, we proposed to use the first program year of the 5-year cap building period in which either the Category A Hospital or Category B Hospital ''begins training'' their requisite threshold FTEs; that is, the program year beginning after December 27, 2020 in which at least 1.0 FTE begins to train at Category A Hospital, and the program year beginning after December 27, 2020 in which more than 3.0 FTEs are trained at Category B Hospital. Then, as 42 CFR 413.79(e)(1) states, we proposed to calculate the FTE resident caps based on the sum of the products of the highest number of FTE residents in any program year during the fifth year of the first new program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program. The adjustment to each qualifying hospital's cap for new residency training program(s) would be equal to the sum of the products of—

- The highest total number of FTE residents trained in any program year during the fifth year of the first new program's existence at all of the hospitals to which the residents in the program rotate;
- The number of years in which residents are expected to complete the program, based on the minimum accredited length for each type of program.
- The ratio of the number of FTE residents in the new program that trained at the hospital over the entire 5-year period to the total number of FTE residents that trained at all hospitals over the entire 5-year period.

We will issue instructions to the MACs and to hospitals to provide for an orderly process of request and review for the purpose of receiving replacement FTE resident caps. The MACs of the Category A and Category B Hospitals will review the FTEs reported in the Medicare cost reports, as well as rotation schedules, information regarding any nonprovider-site training, and accreditation information, etc.) to determine at what point the requisite threshold of FTE residents are trained. As required under 42 CFR 413.20 and 413.24, hospitals must provide sufficient documentation to ensure proper payment (for GME, this includes, but is not limited to, rotation schedules and training agreements, and ACGME accreditation information).

Prospectively, consistent with new section 1886(h)(4)(H)(i)(II) of the Act, we proposed not to establish permanent FTE resident caps for hospitals training residents in new programs begun on or after December 27, 2020, until we determine that in a cost reporting period beginning on or after December 27, 2020, the hospital trains at least 1.0 FTE in a new medical residency program. We proposed to amend the regulations at 42 CFR 413.79(e) to reflect this new provision. We proposed this for all hospitals that do not yet have caps triggered. Therefore, permanent FTE caps for new programs would no longer be triggered if the amount of FTEs being trained by a hospital in the new program equates to less than 1.0 FTE.

As with the resetting of the PRAs, newly added section 1886(h)(4)(H)(i)(V) states that as appropriate, the Secretary may consider information from any cost reporting period necessary to make such an adjustment to the limitation. Going forward, we proposed to continue to be consistent with our existing predicate fact regulations at 42 CFR 405.1885, such that we would not reopen cost reports beyond their 3-year reopening period, but would refer to and use whatever contemporaneous documentation we would need to establish the FTE resident caps.

We invited comments on our proposals regarding resetting the applicable PRAs and FTE resident caps. Following are the comment summaries and our responses:

Comment: Many commenters expressed support for our proposals for defining Category A and Category B hospitals and how we would reset PRA and cap.

Response: We appreciate the commenters' support for our proposals.

Comment: Several commenters were concerned with the CMS suggestion that Medicare Audit Contractors (MACs)

could use ''predicate facts'' to establish a new FTE resident amount, using whatever ''contemporaneous documentation we would need to establish a PRA'' or ''contemporaneous documentation we would need to establish the FTE resident caps.'' (p. 25522, 25524). This leads to confusion as to how and why CMS will decide which facts are predicate facts, and which ones are not. Commenters stated that hospitals may be discouraged from availing themselves of the opportunities set out in section 131 of the CAA if MACs may find records of past training that will leave them with an extremely low PRA or FTE cap. They requested clarification as to how CMS and the MACs will decide what predicate facts are relevant, as well as assurances that MACs will not be encouraged to search for predicate facts that may suppress hospitals' GME support from Medicare.

Response: We believe the commenters misinterpreted the language in the proposed rule regarding ''predicate facts.'' In the proposed rule, we did not propose any new policy regarding predicate facts, nor did we propose any new review procedures that are different from already existing policy. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25522), we merely proposed to ''continue to be consistent with our existing predicate fact regulations'' at 42 CFR 405.1885, under which our policy has been to refer, but not make changes, to a hospital's ''true'' base year under 42 CFR 413.77(e), even if that base year cost report is beyond the 3-year reopening rules. . . . Going forward, we propose to continue to be consistent with our existing predicate fact regulations, such that we would not reopen cost report9s beyond their 3-year reopening period, *but would refer to and use whatever contemporaneous documentation we would need to establish a PRA*'' (emphasis added). This means that the MACs are not hindered by the fact that a cost report is not reopenable, but instead have the flexibility to still consider documentation available from that time frame of that non-reopenable cost report. Accordingly, hospitals that believe they have PRAs set based on a small amount of FTEs, and/or have small FTE caps from a cost report prior to enactment more likely have nothing to lose, and would gain from providing contemporaneous documentation to the MAC for an assessment of its reset eligibility. If a hospital does not provide documentation and does not engage with the MAC at all, then it certainly would be left with a PRA or caps that it believes is ''low''. The intent of section 131 of the CAA is to provide reset opportunities where there previously were none. Nevertheless, as with existing policy, documentation that hospitals provide to the MAC must meet sufficiency standards; newly added clause 1886(h)(2)(F)(v) does not include an exceptions language waiving otherwise standard documentation practices. In response to the following comments, we include more details on the types of documentation that we require or consider acceptable.

Comment: Many commenters provided feedback regarding the review process CMS and the MACs would use to determine eligibility for PRA or FTE cap resets. Several commenters stated they believe the public should have an opportunity to comment on the process before it is finalized by CMS, perhaps even via an interim final rule with comment period. Commenters also expressed concerns and confusion as to which hospitals will be eligible for PRA or cap resets, and that hospitals that do meet the statutory criteria could be ''overlooked'' by the MACs for possible eligibility for a reset. Some commenters urged CMS to publish a list of all hospitals that may have inadvertently triggered a PRA or caps. The following are some scenarios that the commenters posited:

- What if a hospital did not report a small number of FTE residents on its cost report because it was under the impression that it had not established a new residency program and was not eligible for Medicare DGME or IME reimbursement, and the hospital has received a notice of provider reimbursement for that cost reporting period?
- How would CMS treat a hospital that did not report its low number of FTE residents on an old cost report because it did not believe it was eligible for DGME or IME reimbursement; or that did not report residents but if they had, would have a $0 or minimal PRA and low FTE cap?
- What does it mean to ''have'' a PRA or ''have'' FTE caps ''as of enactment?''
- How would CMS treat hospitals that trained a resident but never reported FTEs on their cost reports?
- What if a hospital triggered a PRA but the MAC did not determine and finalize a PRA on a settled cost report?
- What if a hospital's cap building period was triggered prior to enactment, but the 5-year window closed in a cost report after enactment?
- What type of documentation would CMS require, given that the statutory provision stretches back to determinations made in 1996, and contemporaneous documentation from the time period of the cost report may be difficult to obtain?

Response: We acknowledge there are complexities in implementing section 131 of the CAA, and believe the commenters raised fair points in their comments. In general, the primary challenges we and the MACs face in implementing section 131 of the CAA are managing myriads of review requests in an efficient and timely manner, competing MAC priorities for review, and dealing with old documentation, most likely from cost reports that are no longer within the 3-year reopening period. Our final policies try to balance these considerations. We believe that it is incumbent on a hospital to approach its MAC to request a PRA or cap reset; we are not instructing MACs to reach out to individual hospitals. We also distinguish between cost reports that are no longer reopenable, cost reports that have been settled but are still open or reopenable, and cost reports that have not yet been settled.

- Settled But Open or Reopenable Cost Reports

First, in this final rule with comment period, to manage the volume of review requests, we are finalizing policies related to PRA and FTE cap determinations from cost reports that have been settled but are still open or reopenable, and cost reports that have not yet been settled, with one exception related to the 1996 FTE caps (explained in greater detail in this section). We believe the MACs' workload will be considerable from these relatively more recent categories of cost reports alone, and in order to spread the workload, we will instruct MACs to first only accept PRA or FTE cap review requests from hospitals where the base year or cap setting cost report is open or reopenable.

We are seeking comment on how to handle reviews of PRAs or FTE caps from cost reports beyond the 3-year reopening period (with the exception of Category A and Category B hospitals that agree with the HCRIS posting, as discussed below).

(1) Use of HCRIS To Assist in Determining Reset Status

On the points raised by commenters about which hospitals will be eligible for PRA or cap resets, and that CMS should publish a list of hospitals and their status, we will post a file on the CMS website containing an extract of the HCRIS cost report worksheets on which the FTE counts, caps, and PRAs, if any, would have been reported, starting with cost reports beginning in 1995 (although as we stated previously,

we are instructing MACs to only first accept reviews of PRAs or FTE caps from open or reopenable cost reports, with the exception of a Category A hospital or a Category B hospital that agrees with what is/is not reported in the HCRIS posting). This file will be made available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/IPPS-Regulations-and-Notices.* Click on the link on the left side of the screen associated with the appropriate final rule home page or ''Acute Inpatient—Files for Download.'' This file will also be made available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME.* Use of the HCRIS extract provides a national, standard source for MAC determinations.

If a hospital wishes to receive a PRA or cap determination from its MAC for a possible reset of an open or reopenable cost report, the hospital must consult the web posting first. In cases where no PRA or caps are reported on a settled cost report, or when PRAs or caps are reported without any FTEs, and cost report is settled but reopenable, the hospital gets the benefit of a reset without further review by the MAC. Examples of hospitals that would qualify for a reset based on the HCRIS extract without need for further MAC review are as follows:

- The hospital's cost report in HCRIS that ended on or before December 31, 1996 shows an FTE count of less than 1.0 for either IME or direct GME (Category A).
- The hospital's cost report in HCRIS that began on or after October 1, 1997, and before enactment of section 131 of CAA shows an FTE count of not more than 3.0 for either IME or direct GME (Category B).
- A hospital's employee(s) recall that residents were trained at the hospital, but no FTEs were reported on any settled Medicare cost report, as shown in HCRIS.
- A hospital where FTEs are reported on a settled cost report, but the FTE cap lines are not filled (this hospital would be eligible for new FTE caps).
- A hospital with FTEs reported on a settled cost report, but the PRA lines are not filled in on that earliest cost report where FTEs are reported (this hospital would be eligible for a new PRA).
- A hospital with a PRA reported on a settled cost report, but no FTEs are reported on the earliest cost report in which the PRA is reported, so the amount of FTEs used to determine that PRA cannot be determined (this hospital would be eligible for a new PRA).

We believe that allowing resets in the circumstances stated previously demonstrates our willingness to fulfill Congressional intent to allow eligible hospitals their second chance at meaningful IME and direct GME reimbursement, and further indicates that we and the MACs intend to be fair and reasonable throughout the implementation process. As we stated in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25523), MACs would calculate the replacement PRAs and/or FTE resident caps using the existing regulations in place at 42 CFR 413.77(e) and 42 CFR 413.79(e)(1), but after the MAC confirms that either the Category A Hospital or Category B Hospital trains their requisite threshold FTEs in a new program(s) started after December 27, 2020.

(2) One-Time Deadline To Request Reconsideration and Review by the MAC for Possible Category B Hospitals

If, for open or reopenable cost reports, there is a PRA and/or FTE caps reported on the HCRIS web posting, and the potential Category B hospital believes its PRA in fact was established based on not more than 3.0 FTEs, or its IME and/or direct GME FTE caps were based on not more than 3.0 FTEs, a hospital has a 1-time opportunity to request reconsideration by its MAC which must be submitted electronically and received by the MAC on or before July 1, 2022. We are providing this lead time for this 1-time submission to assist hospitals in ensuring that they include complete and unambiguous documentation supporting their assertion that the HCRIS cost report information is incorrect. We also believe this approach encourages only review requests with realistic chances for reset eligibility under section 131 of the CAA. (See response regarding documentation required). The MAC would review the information within a specified timeframe to be determined by CMS and make a determination as to the hospital's eligibility for a PRA and/or FTE cap reset based on the adequacy of the documentation submitted by July 1, 2022. The decision issued by the MAC to the hospital would be final. If the MAC determines that the FTEs reported are greater than 3.0 respectively, the hospital is NOT eligible for a PRA or FTE cap reset. Hospitals that disagree with the MAC's determination could appeal to the Provider Reimbursement Review Board for review, assuming that all conditions for appeal are met.

(3) Cost Reports Not in HCRIS or Not Yet Settled

There may be situations where a cost report is not in HCRIS web posting, or even if the cost report is in the HCRIS web posting, there is no PRA or no FTE caps reported because the cost report has not yet been settled and/or the MAC has not yet determined the PRA or the FTE caps. Such a hospital must submit a request to the MAC by July 1, 2022 requesting that the MAC issue a determination regarding possible reset eligibility for the PRA and/or FTE caps using cost reports that began prior to enactment. The review request must be received by July 1, 2022, and must include complete and unambiguous documentation for FTE counts and for FTE cost and payment information (see response regarding documentation requirements). The MAC would use existing regulations at 42 CFR 413.77(e) and 42 CFR 413.79(e)(1) to determine the hospital's PRA and FTE caps from the cost report(s).

For cost reports that began during CY 2020 (but still prior to enactment of the CAA) and are subject to PHE submission deadlines, the hospital must file its cost report with complete and unambiguous supporting GME documentation to the MAC by July 1, 2022 in order to receive consideration for possible PRA or FTE cap reset. MACs will reject incomplete or untimely submissions, with no opportunity for a later or 2nd MAC review.

If the MAC determines that the FTEs are greater than 3.0, the hospital is NOT eligible for a PRA or FTE cap reset. Hospitals that disagree with the MAC's determination may appeal to the Provider Reimbursement Review Board assuming that all conditions for appeal are met.

Accordingly, for the purpose of implementing section 131 of the CAA, in response to the comment asking what it means to ''have'' a PRA or ''have'' FTE caps ''as of enactment,'' we are clarifying that ''having a PRA'' means that there is a PRA reported in HCRIS from a cost reporting period beginning prior to enactment, or if not in HCRIS or not yet determined, the MAC determines the PRA based on the hospital's request by July 1, 2022, but from a cost reporting period beginning prior to enactment. If the PRA base period cost report begins prior to enactment, we believe it is acceptable if it ends after enactment. This is because section 131(a)(iii) states, '' . . . in the case of a hospital that, as of such date of enactment, has an approved FTE resident amount . . . in any cost reporting period beginning on or after

October 1, 1997, and before the date of enactment . . .'' (emphasis added). Thus, a hospital's PRA could have been initiated when training no more than 3.0 FTEs in a cost report beginning prior to enactment on May 1, 2020, and ending April 30, 2021 (after enactment). Similarly, we are clarifying that ''having FTE caps as of enactment'' means that the 5-year cap building window would close in a cost reporting period that *began before enactment,* although the cost report may end after enactment. This is because section 131(b)(IV) states, ''in the case of a hospital that, as of the date of the enactment of this subclause, has a limitation under subparagraph (F), based on a cost reporting period beginning . . . before such date of enactment . . .'' (emphasis added). For example, if a hospital's 5-year cap building window closed June 30, 2021, but that was during the hospital's cost report beginning October 1, 2020 (prior to enactment) and ending September 30, 2021 (after enactment), this hospital would ''have'' FTE caps as of enactment.

(4) PRA Base Periods Initiated Prior to Enactment, With Cap-Building Period Ending After Enactment

Commenters requested clarification regarding when a hospital's cap building period was triggered prior to enactment, but the 5-year window closes in a cost report with a *start date after enactment.* The following policies apply. As we stated previously, in response to the comment asking what is means to ''have'' a PRA and ''have'' FTE caps ''as of enactment,'' if the PRA base period cost report begins prior to enactment, we believe it is acceptable if it ends after enactment. Similarly, ''having FTE caps as of enactment'' means that the 5-year cap building window would *close in a cost reporting period that began before enactment,* although the cost report may end after enactment. That is, the 5-year cap building window would have to close during a cost reporting period that *started prior to enactment.* For example, if a hospital's 5-year cap building window closed June 30, 2021, but that was during the hospital's cost report beginning October 1, 2020 (which started prior to enactment) and ending September 30, 2021 (after enactment), this hospital would ''have'' FTE caps as of enactment. Under existing regulations at 42 CFR 413.79(e)(1), the year for determining new program caps is the third year of the new program's existence for programs started prior to October 2012, and the fifth year of new program's existence for programs started after October 2012. Therefore, only hospitals whose *third or fifth program year ENDS in a cost reporting period that started PRIOR to enactment* would qualify under section 131 of the CAA for a possible FTE cap reset. The law does not allow consideration for FTE cap reset for a hospital whose FTE cap setting year (that is, the cost report following the close of the 5-year cap building window) begins after enactment. Therefore, there can be situations where a hospital might be eligible for a PRA reset, as the PRA base period occurred prior to enactment, while the same hospital is NOT eligible for FTE cap resets, since the relevant cost reporting period for setting that hospital's FTE caps in accordance with 42 CFR 413.79(e)(1) would not even occur until some time after enactment. For example, a hospital for the first time trains 2.0 FTE residents in a new program in its cost reporting period beginning January 1, 2019 and ending December 31, 2019. The new program started on July 1, 2019. This FYE December 31, 2019 would be the PRA base period, so the hospital would ''have'' a PRA ''as of enactment''. The 5-year cap building window would end on June 30, 2024, during the hospital's cost report that began January 1, 2024. Since the 5-year cap building window ends in a cost report that starts after enactment, this hospital does not have a FTE cap ''as of enactment,'' and would not qualify under section 131 for an FTE cap reset.

Therefore, hospitals submitting documentation to their MACs by July 1, 2022 for a determination regarding PRA or FTE cap reset must include documentation showing that the PRA base period started prior to December 27, 2020, and that the 5-year cap building window ended in a cost reporting period that started prior to December 27, 2020. Such documentation includes the following:

- The date that residents in a new program first rotated into this hospital (see August 27, 2009 IPPS final rule (74 FR 43908) for definition of new program).
- Whether that date was the first time residents began training at ANY rotational site for that program, or whether residents in that program had previously rotated to other sites before rotating into this hospital.

Comment: A commenter requested clarification on what documentation would be needed to demonstrate/obtain eligibility for a PRA or cap reset. The commenter stated that they have cost reports, but no longer have records of IRIS reports or rotation schedules.

Response: We are not creating new or different documentation requirements for the purpose of section 131 of the CAA, but continue to use our existing documentation requirements, discussed previously in the August 29, 1989 final rule (54 FR 40286, 40291 and 40304), the August 18, 2006 IPPS final rule (71 FR 47869, 48077), and implemented at 42 CFR 413.75(d). We stated that a rotation schedule is the primary documentation that can be used to support the direct GME and IME resident counts but other similar documentation may be acceptable (71 FR 48077). The rotation schedule is prepared by the Program Director for each program for each program year. As such, there is only one rotation schedule for each approved program for each program year and *all the hospitals to which the residents in that program rotate must use that same schedule.* 42 CFR 413.78(d) states, ''The information must be certified by an official of the hospital and, if different, an official responsible for administering the residency program.'' If the hospitals to which the residents rotate have other than June 30 FYEs, the hospitals must use two rotation schedules which overlap that FYE.

We are including a list of documents necessary to demonstrate the FTEs from which a PRA would have been calculated or from which a FTE cap would have been calculated. The main documentation needed for FTE cap support and for the FTEs claimed on the earliest cost report which will be used to determine if the hospital meets the less than 1.0 FTE or not more than 3 FTEs requirement for the PRA is: The program approvals; the rotation schedules showing the location of the residents, either within hospitals or nonprovider sites per 42 CFR 413.78(g); the Intern and Resident Information System (IRIS) (to be used only as an audit tool until direct GME and IME counts on the IRIS and the cost report match); a resident's Foreign Medical Graduate Examination in the Medical Sciences certificate (FMGEMS) status for direct GME under 42 CFR 413.75(b) and 42 CFR 413.80; information whether the resident is full-time/part-time at the hospital; agreements between the hospitals and program approval if the resident is floating from another hospital's program.

Documentation to establish a PRA includes payroll and employment data indicating payment of residents' salaries and fringe benefits if the hospital employs the residents, contracts with medical schools or other hospitals which employ the residents specifying the charges to the host hospital for these expenses and related invoices, evidence that the host hospital actually paid the

charges from the medical school or other hospital, documentation of the expenses the host hospital paid for the portion of the teaching physicians' compensation and fringe benefits related to teaching and supervision of the residents, and documentation supporting payment of other Medicare allowable costs that are directly related to operating the program (such as salaries of the program director and other office staff associated with operating the program, and operating and overhead costs directly attributable to training the residents).

We understand that there may be some difficulty involved in procuring documentation in the case where the hospital seeking to reset its low PRA and FTE caps trained the residents for a minimal time, and may not have the official documents such as the rotation schedule. Nevertheless, we want to be clear that unofficial copies or deviations from the official program rotation schedule and other substitutions will not be accepted. Hospitals seeking PRA and cap resets still must meet standard documentation requirements (per 42 CFR 413.20 and 413.24), and will have to work with the program primary clinical sites and program director to obtain definitive FTE information. In an effort to implement section 131 of the CAA in an accurate and administratively feasible manner, it is of utmost importance for hospitals to submit clear and acceptable documentation to their MACs by the July 1, 2022 deadline. The MACs' determinations will be based on documentation received by that date. Hospitals may supplement their documentation up until the July 1, 2022 deadline, but not after that date. We reiterate that we are not creating new or different documentation requirements for the purpose of section 131 of the CAA, but continue to use our existing documentation requirements, discussed previously in the August 29, 1989 final rule (54 FR 40291 and 40304), the August 18, 2006 IPPS final rule (71 FR 48077–78), and implemented at 42 CFR 413.75(d).

Comment: A commenter believed it is not appropriate for CMS to require that a teaching hospital permitted to have its PRA reset use a base period that has already begun at the time of the release of the IPPS proposed rule. The commenter asserted that hospitals want to know how CMS proposes to implement this provision, then see how the rules are finalized, and then avail themselves of the opportunity for a reset as applicable. This commenter requested that CMS permit a hospital to use any base period within the statutory 5-year window, including a base period that begins: (1) After enactment of the CAA; (2) after publication of the IPPS proposed rule; (3) after publication of the IPPS final rule; and (4) after CMS issues instructions to the MAC and the community for carrying out this process. Then, the commenter recommended that CMS allow hospitals to request to have their PRAs reset based on an applicant hospital's next full cost reporting period following approval by CMS of its application and request.

Response: We understand the commenter's point that although hospitals can avail themselves of a PRA reset as early as after the enactment of the CAA, that initial cost report overlapping with or immediately following CAA enactment would still be when the hospital is unaware of how CMS intends to implement section 131 of the CAA. We agree with the commenter that a hospital should have some flexibility in determining the timing of its new PRA base period, to the extent that the statute permits. However, we note, that clause (iii)(II) of section 131 of the CAA directs the Secretary to reset a PRA ''*if* the hospital trains at least 1.0'' FTE or ''more than 3.0'' FTE ''in a cost reporting period beginning on or after such date of enactment and before the date that is 5 years after such date of enactment.'' That is, the timing of the revised PRA base period is dependent upon when the hospital trains at least 1.0 FTE or more than 3.0 FTE (as applicable) in the time frame of after enactment and 5 years after that. We also note that clause (iii)(II) of section 131 of the CAA directs the Secretary to use the methodology in the regulations at 42 CFR 413.77(e) to establish the revised PRA, which typically would mean use of the earliest cost report in which the hospital trains residents in an approved program. Therefore, we do not believe we can provide hospitals with the option to choose *any* cost reporting period occurring during the time frame of after enactment and 5 years after as the new PRA base period. However, we believe we can utilize the flexibility provided by section 131 of the CAA, clause (v), which states, ''As appropriate, the Secretary may consider information from *any* cost reporting period necessary to establish a new FTE resident amount as described in clause (iii)'' (emphasis added). Therefore, we believe it would be fair to allow a hospital *to have the option* of using as its new PRA base period cost report *the first cost reporting period beginning after issuance of this final rule with comment period.* That is, we are finalizing a policy that if the hospital already started training at least 1.0 FTE or more than 3.0 FTEs in a cost reporting period beginning immediately following enactment, the hospital could choose to use either that cost report as the PRA base period, or the hospital could wait to see if the first cost reporting period beginning after issuance of this final rule with comment period may result in a more favorable PRA. If a hospital does not even start training at least 1.0 FTE or more than 3.0 FTEs until a cost reporting period that is *after* the first cost reporting period beginning after issuance of this final rule with comment period (but still within 5 years after enactment), then the hospital would not have a choice as to which cost reporting period to use as its new PRA base period; the hospital must use that second or subsequent cost reporting period after issuance of this final rule with comment period as its new PRA base period. We are revising the regulations at 42 CFR 413.77(e)(1)(iv) accordingly. We are also not requiring in the regulations at 42 CFR 413.77(e)(1) that residents be on duty during the first month of the PRA base period for teaching hospitals receiving a PRA reset, and for new teaching hospitals in general. We believe that requirement is no longer relevant, in light of the statutory focus on when at least 1.0 or more than 3.0 FTEs are trained.

Comment: A commenter noted that throughout the discussion in the proposed rule regarding the opportunity for a hospital to adjust its small IME and direct GME FTE caps, CMS uses words like ''replace,'' or ''reset,'' which implies that CMS would eliminate even the small amount of FTE cap that the hospital already has, and give a different cap. The commenter believed that Congress is directing CMS to allow a qualifying hospital to *add to* its existing direct GME or IME caps (not restart at zero).

Response: We have reviewed the language of section 131 of the CAA, and we note that section 1886(h)(4)(H)(i)(III) of the Act, as added by subsection 131(b), states that ''the Secretary shall *adjust* the limitation''; it does not say 'in lieu of'', as it does for the PRA, under clause 1886(h)(2)(F)(iii) of the Act, as added by subsection 131(a) of the CAA. Accordingly, we agree with the commenter that an eligible hospital would keep its IME or direct GME FTE caps of less than 1.0 or not more than 3.0, and any cap amount based on new programs would be added to the original cap amounts. That is, new caps created based on new programs started after enactment and 5 years after would be

added to the hospital's original caps, while the original PRA would be replaced by a new PRA from a base year after enactment and 5 years after. We are revising the regulations text at 42 CFR 413.79(e)(1)(vi) accordingly, to state that the adjusted FTE cap is equal to the sum of the *original FTE cap and* the products of three factors based on the new program(s).

Comment: A commenter expressed confusion regarding what situations CMS intends to exclude with the restriction that it would not reset the caps for a hospital that ''first began training residents in a new program prior to its cost reporting period beginning on or after enactment and continued to train FTE residents in the new program after enactment'' (86 FR 25522). The commenter was particularly concerned that CMS may be interpreting Congress's intent in using the phrase ''begins training'' to restrict the applicability of section 131 of the CAA to a much smaller set of hospitals than they believe was intended. Other commenters argued that by adding the term ''first'' or ''first time'', in front of ''begins training'' CMS changes the entire meaning of the provision. These commenters asserted that the statute clearly indicates that beginning a new program should be the trigger, and they do not believe requiring a hospital to have never started a new program since its cap was set is in keeping with the statute. For example, it leaves hospitals with a cap of less than 3 (Category B hospitals) that started a new program after that cap was set, but before the law was enacted, with no recourse. The first commenter provided the following example and requested that CMS confirm their understanding that the section 131 of the CAA FTE cap resetting policy would be implemented for a hospital in this situation in the manner described.

Example:

Hospital A, which operates on a cost reporting period of July 1 through June 30, trained residents for the first time as of July 2003. During that residency program year, 2.7 FTE residents from a new internal medicine program established at New Teaching Hospital B rotated to Hospital A.

- Hospital A continued to train that same number of FTE residents from that same program for the subsequent four residency program years. Hospital A did not train any additional residents in its hospital between July 2003 and June 2008. Hospital A had a DGME cap of 2.7 set as of July 1, 2008.
- Hospital A continued to train 2.7 FTE residents from that same internal medicine program established at New Teaching Hospital B every year between July 2008 and June 2018.
- Beginning in July 2018 and during each residency year through June 2022, Hospital A trains 10.0 additional FTE residents from Existing Hospital C in the specialties of family medicine, emergency medicine, and general surgery. The family medicine residents are training in a newly established residency program that first began training residents in July 2018 while the emergency medicine and general surgery residents are training in and rotating from longstanding, existing residency programs.
- In its most recent cost report, Hospital A reports training 12.7 FTE residents and reports a DGME cap of 2.7.
- Hospital A applies to CMS to have its cap reset under section 131 of the CAA's provision (based on having a cap of 2.7).
- Beginning in July 2022, Hospital A establishes a new three-year family medicine program approved for 15 positions, with 5 FTE residents in each program year with all FTE resident time countable and no rotations to any other hospitals.
- Beginning in July 2025, Hospital A establishes a second new program, a 5-year general surgery program approved for 30 positions, with six FTE residents in its initial program year (July 2025 to June 2026) with all FTE resident time countable and no rotations to any other hospitals.

The commenter requests that CMS confirm that Hospital A's DGME cap would be reset as of July 2027 as follows:

2.7 (existing DGME cap prior to enactment of CAA)
+ 15 (representing cap adjustment for family medicine program started in July 2022)
+ 30 (representing cap adjustment for general surgery program started in July 2025)
= 47.7 (new DGME cap as of July 2027)

Response: We have reviewed the statute and we are convinced by the commenters that the statute does *not* require that a hospital wait to begin a new program until after enactment in order to be considered an eligible Category A or Category B Hospital. We are changing our proposed policy to not disqualify *a hospital that started a new program prior to enactment from being eligible for a cap reset, so long as it also starts a new program after enactment.* However, we would only give the cap adjustment for new programs started after enactment, not before enactment. Thus, Hospital A in the commenter's example would qualify as a Category B hospital, but its FTE resident caps of 2.7 would be adjusted upward to reflect only the family medicine program and general surgery program started after enactment (in 2022 and 2025 respectively), and NOT the family medicine program started in 2018.

Comment: A commenter requests clarification on the possible confusion of the use of ''program year'' and ''cost reporting year'': In one part of the preamble, CMS states that ''adjustments will be available for a hospital that begins training more than 1.0 or 3.0 FTE in a *program year* beginning on or after the date section 131 of the CAA was enacted.'' The commenter stated this inconsistency is mirrored in the proposed regulatory changes to DGME and IME caps at 42 CFR 413.79(e)(1)(vi) and 42 CFR 412.105(f)(1)(vii)(B). The commenter requested that this be remedied or explained.

Response: We are not sure to which inconsistency the commenter is referring. We note that section 131 of the CAA specifically uses the term ''program year.'' That is, section 131(b) of the CAA (adding new section 1886(h)(4)(H)(i)(III) of the Act), states, ''In applying this clause in the case of a hospital that, as of the date of enactment of this subclause, has a limitation . . . of less than 1.0 full-time equivalent resident, the Secretary shall adjust the limitation . . . if . . . the hospital begins training at least 1.0 full time equivalent residents in a program year beginning on or after such date of enactment . . .'' (emphasis added). Similar language is at section 1886(h)(4)(H)(i)(IV) of the Act, as added by the CAA, applicable when a hospital begins training more than 3.0 FTEs. Regardless, we are making changes to conform to our final policies at 42 CFR 413.79(e)(1)(vi) and 412.105(f)(1)(vii)(B).

Comment: Some commenters stated that CMS should ensure that the concept of ''community support and redistribution of costs'' not be applied under this provision. This principle, stating that Medicare will not reimburse for situations after another entity has paid for resident training, is not appropriate because it was statutory and regulatory actions that prevented hospitals from appropriate reimbursement for residency positions from Medicare. At a minimum, CMS should change its rules to allow hospitals in this situation to count the FTEs in the new program or programs established following enactment in setting its new cap during its 5-year cap-setting window.

Response: We disagree with the commenters that we should (even if we

could) waive community support principles at 42 CFR 413.81, but also disagree with commenters that it would even be an obstacle. After all, the law would readjust the cap based on ''new'' programs started by the hospital and if the program is new and the hospital is incurring the cost from the start, then there is no concern of redistribution or community support.

Comment: A few of the commenters argued that CMS's proposal limits eligibility to the Category A and Category B criteria set forth in subparagraphs iii and iv of CAA 2021 for hospitals that previously trained residents in the distant past. The commenters believed it was a critical omission, and that nothing in the drafting of subparagraphs ii, iii, and iv of the Act as added by the CAA indicates that a hospital's eligibility is conditioned solely on whether a hospital falls into Category A or Category B. Otherwise, any hospital that has ever reported FTE residents on a cost report but was unable to meet the technical requirements of Category A or Category B would be barred from establishing a new FTE resident cap, which we believe is contrary to the legislative intent of the Act. Therefore, the commenters requested that CMS clarify that a hospital that has previously reported FTE residents on a cost report may pursue a new FTE resident cap determination under a new residency program pursuant to subparagraph ii of the Consolidated Appropriations Act, 2021.

Response: We do not believe Congress gave us the authority to provide relief or waivers to categories beyond A and B. We believe that the CAA is unequivocally clear about the size of the caps that would be eligible for a reset; that is, for hospitals with caps set based on its 1996 cost report, the cap must be less than 1.0 FTE, and for hospitals with caps set in a cost reporting period between 1997 and prior to enactment, the cap must not be more than 3.0 FTE.

Comment: A commenter noted that section 131 of the CAA states, ''A hospital shall report full-time equivalent residents on its cost report for a cost reporting period if the hospital trains at least 1.0 full-time equivalent residents in an approved medical resident training program or programs in such period.'' The commenter questioned how a hospital would know that it ''shall'' and what happens if it does not. The commenter also questioned whether these hospitals would again have PRAs of $0 and acquire caps without knowing it, after the 5-year window included in the legislation.

Another commenter stated that PRAs have not been proactively assigned to every hospital in the US, and under current regulations a PRA of $0 is only discovered and established when a resident is first reported on a cost report. The commenter requested that until such time as hospitals have the opportunity for a certified audit financed by CMS prior to training residents, we recommend that all hospitals without a PRA or cap be assigned a PRA that is ''the updated weighted mean value of per resident amounts of all hospitals located in the same census region as that term is used in subpart D of part 412 of this subchapter,'' or until a hospital can demonstrate its ability to train residents for less than that amount.

Response: Regarding how to treat hospitals in the future that inadvertently train small numbers of residents, we note that section 131 of the CAA specifies that ''for cost reporting periods beginning on or after enactment, a hospital shall report full-time equivalent residents on its cost report if the hospital trains at least 1.0 full-time equivalent residents in an approved medical residency program or programs in such period.'' In the proposed rule, we interpreted this to mean that Congress was putting hospitals on notice that they are obligated to be aware of and report their residents to CMS on the cost report for training as minimal as 1.0 FTE. We also believe that section 131 of the CAA is unequivocally clear that a qualifying hospital's cap or PRA must be in effect ''as of enactment,'' which means that it would have been (or should be determined) from a cost reporting period that started *prior* to enactment. Thus, we believe section 131 of the CAA is *not meant to provide relief to hospitals that trigger low caps or PRAs after enactment.* As stated previously, we are also no longer requiring in the regulations at 42 CFR 413.77(e)(1) that residents be on duty during the first month of the PRA base period for teaching hospitals receiving a PRA reset, and for new teaching hospitals in general. We are finalizing our proposed interpretation of these clauses, and accordingly, we do not believe we have flexibility to ''forgive'' or ''ignore'' caps or PRAs triggered after enactment, even when the training is not more than 1.0 FTE.

Regarding the comment that prior to the MAC audit for a new teaching hospital's PRA, the hospital should be assigned the census region PRA, we note that policy is already in effect per Transmittal 1923, CR 10240 (page 5), which states: ''. . . the MAC shall use the latest available census region PRA issued by CMS for the census region in which the new teaching hospital is located, updated for inflation to the base period of the new teaching hospital, for the purpose of calculating and paying DGME interim rates. However, once the hospital submits its base year cost report, the MAC shall calculate and assign the appropriate PRA to the new teaching hospital (as part of the normal cost report settlement process for the new teaching hospital).''

Comment: A commenter requested that once a hospital resets its FTE cap under section 131 of the CAA, it should have certainty that no audits will revisit prior training, while another commenter stated that redeterminations under section 131 of the CAA should be binding unless the provider concealed material information, or the provider appeals the determination. Another commenter recommended that hospitals with yet undiscovered low PRAs be subject to limited lookback (for example, 3 years) and only set a PRA when beginning the training of residents in the future. An additional commenter noted that CMS requires records of cost reports to be retained in their original or legally reproduced form for 5 years after the closure of the cost report, and strongly recommended that CMS use the record retention requirements to set a lookback window of 5 years when evaluating the cost reports of hospitals that are seeking to set a new PRA under these rules.

Response: As we stated in response to a previous comment, we must manage a significant workload resulting from implementation of section 131 of the CAA, and therefore, we are taking steps to try to mitigate that workload, including instituting a one-time deadline of July 1, 2022 for hospitals to request a reset for their PRAs or FTE caps. MACs will not consider late documentation, nor will MACs conduct second reviews. Hospitals that disagree with the MACs' determinations may appeal to the PRRB, assuming conditions to appeal are met. In addition, in this final rule with comment period, to manage the volume of review requests, we are finalizing policies related generally to more recent, open cost reports, and would accept comments after publication of this final rule with comment period regarding how to address the use of older cost reports to which some kind of limited ''look back'' policy could be applicable. Thus, we believe our final policy of one-time review is consistent with the commenters' requests that the MACs' determinations should not be revisited, and they should be binding,

unless fraud is suspected. With regard to hospitals with ''yet undiscovered low PRAs,'' these hospitals would follow the methodology outlined previously, where hospitals would use the HCRIS posting to determine their status (or follow the policy in the section regarding cost reports not yet in the HCRIS posting or not yet settled).

A comment was submitted regarding the regulations related to new teaching hospitals and the impact of the ongoing pandemic and public health emergency (PHE). We are not addressing this comment at this time, as it is not in the scope of the proposed rule.

f. Summary of Finalized Policies With Regard to Section 131 of the CAA

After consideration of comments we received, we are finalizing the following policies with regard to section 131 of the CAA:

- In this final rule with comment period, we are finalizing policies for resets related to cost reports that are open, reopenable, or not yet settled. We will post a file on the CMS website containing an extract of the HCRIS cost report worksheets on which the FTE counts, caps, and PRAs, if any, would have been reported, starting with cost reports beginning in 1995. We are also seeking public comment regarding how to handle reviews of PRAs or FTE caps from cost reports that are beyond the 3-year reopening period (with the exception of Category A and Category B hospitals that agree with the HCRIS posting).
- Hospitals must first consult the HCRIS posting on CMS's website to determine reset eligibility. MACs will not reach out to hospitals.
- In cases where no PRA or caps are reported on a settled cost report, or when PRAs or caps are reported without any FTEs, and a cost report is settled but reopenable, the hospital gets the benefit of a reset without further review by the MAC.
- If, for open or reopenable cost reports, there is a PRA and/or FTE caps reported on the HCRIS web posting, and the hospital believes its PRA in fact was established based on not more than 3.0 FTEs, or its IME and/or direct GME FTE caps were based on not more than 3.0 FTEs, a hospital has a 1-time opportunity to request reconsideration by its MAC which must be submitted electronically and received by the MAC on or before July 1, 2022.
- Hospitals that disagree with the 1-time MAC determination may appeal to the PRRB, assuming all conditions for appeal are met.
- Eligible hospitals for resets are those only that have a PRA base period that started prior to enactment and/or FTE cap building window that occurred/closed in a cost reporting period that started prior to enactment (December 27, 2020).
- FTE cap resets will only be based on new programs started after enactment and 5 years after (by December 26, 2025).
- Hospitals that qualify for a PRA reset may use as the new PRA base period either the earliest cost reporting period beginning between enactment and 5 years after in which they train FTES in a new program, or the first cost reporting period beginning after issuance of this final rule with comment period. In any case, residents need not be on duty during the first month of the cost reporting period from which the per resident amount is established.
- Effective with cost reporting periods beginning on or after December 27, 2020, a PRA would be established if a hospital trains less than 1.0 FTE as a result of participating in a Medicare GME affiliation agreement. Otherwise, no PRA would be established until a hospital trains at least 1.0 FTE. In any case, residents need not be on duty during the first month of the cost reporting period from which the per resident amount is established.
- Effective with cost reporting periods beginning on or after December 27, 2020, a hospital must report training of less than 1.0 FTE on its Medicare cost report if that training is as a result of participating in a Medicare GME affiliation agreement. Otherwise, a hospital must report FTEs on its Medicare cost report when it trains at least 1.0 FTE.
- Hospitals eligible to reset their PRAs would get a new PRA replacing their old PRA(s); hospitals eligible to reset their FTE caps would receive an FTE cap adjustment equal to the sum of the original FTE cap and the new program FTE cap adjustment.

We are finalizing regulation text changes to the following:

- 42 CFR 413.77(e)(1)(iv) to reflect that hospitals qualifying for a PRA reset may use as the new PRA base period either the earliest cost reporting period beginning between enactment and 5 years after in which they train FTEs in a new program, or the first cost reporting period beginning after issuance of this final rule with comment period.
- 42 CFR 413.78(b) regarding when a hospital must report FTEs on its Medicare cost report.
- 42 CFR 413.79(e)(1) and (8) to reflect the circumstances under which a new program FTE cap would be established, and how an adjusted FTE cap would be calculated.

C. Organ Acquisition Payment Policies

1. Background

a. History of Medicare Organ Acquisition Policies

The Medicare Program supports organ transplantation by providing an equitable means of payment for the variety of organ acquisition services. Medicare excludes organ acquisition costs from the inpatient hospital prospective diagnosis-related group (DRG) payment for an organ transplant, and separately reimburses transplant hospitals [4] (THs) for the organ acquisition costs on a reasonable cost basis (42 CFR 412.2(e)(4) and 412.113(d)).[5]

Medicare's current organ acquisition policy is modeled after the kidney acquisition policy that was implemented for kidney transplants following the Social Security Amendments of 1972 (Pub. L. 92–603) that extended Medicare coverage to individuals with end stage renal disease (ESRD) who required dialysis or transplantation. In July 1973, CMS (then the Bureau of Health Insurance [6] (BHI)) issued Intermediary Letters (ILs) which set forth procedures and policies for Medicare reimbursement for kidney transplants. The IL 73–25 [7] (July 1, 1973) set forth policies for the reimbursement for kidney transplants and dialysis, including policies for hospital reimbursement for the acquisition of a kidney from cadaveric and living donors for transplant into a Medicare beneficiary. In IL 73–25, the BHI commented that as it received and analyzed data and studied reimbursement methodology, it would develop and issue more detailed reimbursement instructions to support the delivery of quality services in an efficient manner. In July 1974, the BHI issued IL 74–23,[8] which set forth

[4] Under 42 CFR 482.70 a transplant hospital is a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

[5] In accordance with 42 CFR 412.113(d), organ acquisition costs incurred by hospitals with approved transplant programs are paid for on a reasonable cost basis.

[6] To implement the Medicare statute, the Social Security Administration was reorganized and the Bureau of Health Insurance (BHI) was established on July 30, 1965. The BHI then became responsible for the development of health insurance policy before the creation of the Health Care Financing Administration (HCFA), later renamed the Centers for Medicare & Medicaid (CMS). CMS Milestones 1937–2015 (July 2015).

[7] *https://www.cms.gov/medicare/acute-inpatient-pps/fy-2022-ipps-proposed-rule-home-page.*

[8] Id.

additional policies for Medicare reimbursement of kidney acquisition costs, many of which remain in place currently. In 1978, to clarify that the Secretary of the Department of Health and Human Services (the Secretary) has authority and to provide reimbursement for the costs incurred in connection with kidney donations, Congress enacted legislation that added special provisions relating to coverage under the Medicare Program for ESRD (Pub. L. 95–292). This legislation added section 1881 to the Social Security Act that set forth Medicare payment for kidney transplantation and the coverage of kidney procurement costs and living donor expenses, including Part A and Part B benefits for the living donor.[9] As CMS stated in the 1978 **Federal Register** (43 FR 44803), the purpose of section 1881 of the Act was to encourage kidney transplantation and the scope of Medicare benefits to cover all reasonable preparatory, operation and post-operation expenses associated with a kidney donor, through the actual period of recovery.

Over the years through various rulings and national coverage determinations, Medicare has added coverage for transplantation of non-renal organs such as heart, liver or lungs; we modeled our reimbursement for the acquisition costs for non-renal organs based on our earlier kidney acquisition policies. Medicare's organ acquisition payment policy is mostly set forth in CMS Pub. 15–1, chapter 31,[10] the Provider Reimbursement Manual (herein referred to as PRM) and in Medicare regulations at 42 CFR 412.2(e)(4), 412.100, 412.113(d), 413.200, 413.202, and 413.203. The entities involved in organ acquisition, which we will further define and discuss herein, are THs, donor community hospitals (Medicare-certified non-transplant hospitals), organ procurement organizations (OPOs), some of which are hospital-based OPOs (HOPOs), and histocompatibility laboratories.

Section 1102 of the Act authorizes the Secretary to publish rules and regulations necessary for the efficient administration of the functions with which the Secretary is charged under the Act. Section 1871(a) of the Act authorizes the Secretary to prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title. In this final rule, we are codifying into the Medicare regulations some longstanding Medicare organ acquisition payment policies, with clarifications where necessary, and codifying some new organ acquisition payment policies with modifications based on public comments. We are finalizing our proposals to move existing organ acquisition payment regulations, or portions of existing kidney acquisition regulations, within title 42 of the CFR part 412, subpart G and part 413, subpart H, to a new part 413, subpart L, so that all organ acquisition payment policies are housed together. We are also finalizing our proposal to codify into new subpart L certain policies pertaining to organ acquisition, as set forth in section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173) and section 17006 of the 21st Century Cures Act (Pub. L. 114–255), in accordance with their statutory effective dates. We are also finalizing our proposal to make conforming changes and technical corrections to the regulations, where necessary.

We are aware of OIG audits reporting that some OPOs have billed the Medicare Program for unallowable expenditures.[11] There have also been recent Congressional oversight interest and inquiries into OPO financial management.[12] We believe the provisions that follow will provide clarity and allow providers and stakeholders to more easily locate and understand organ acquisition payment policy, resulting in more accurate payment based on reasonable cost principles.

b. Overview of Medicare Reimbursement in Transplantation

Medicare reimburses THs for organ acquisition costs, the transplant surgery, inpatient, and post-transplant costs for the Medicare recipients, but through different payment systems. Medicare Part A pays for hospital costs of a transplant surgery and certain follow-up care through a DRG payment and the organ acquisition costs associated with a transplant on a reasonable cost basis. In general, Medicare Part B pays for the physician services and other services furnished to eligible Medicare beneficiaries. CMS established Conditions of Participation (CoP) for hospitals under 42 CFR part 482, subpart E. Transplant programs, located within a TH that has a Medicare provider agreement, must meet the applicable hospital CoPs at §§ 482.1 through 482.70 and the transplant program CoPs, located at §§ 482.72 through 482.104, and additional requirements in order to be eligible to participate in the Medicare Program.

OPOs coordinate the procurement, preservation and transportation of organs from deceased donors, and maintain a system for locating prospective recipients for organ transplantation. Section 1138 of the Act sets forth hospital protocols for the identification of potential organ donors and the standards for OPOs. To be an OPO, an entity must meet the applicable requirements of both the Act and the Public Health Service Act (the PHS Act). The statutory functions of an OPO are also set forth in 42 U.S.C. 273; section 371 of the PHS Act. Section 1138(b) of the Act provides the statutory qualifications and requirements that an OPO must meet in order to be reimbursed under the Medicare or Medicaid Program for certain organ procurement costs. CMS established Conditions for Coverage (CfCs) OPOs must meet in order to receive payment under Medicare or Medicaid for organ procurement costs in the regulations at 42 CFR part 486, subpart G. Section 1138(b)(1)(A) of the Act specifies that payment may be made for organ procurement costs only if the agency is a qualified OPO operating under a grant made under section 371(a) of the PHS Act or has been certified or re-certified by the Secretary as meeting the standards to be a qualified OPO. Among those requirements, each OPO must be a member of, participate in, and abide by the rules and requirements of the Organ Procurement Transplantation Network (OPTN) that are approved by the Secretary (see 42 CFR 486.320).

Medicare reimburses THs for organ acquisition costs under reasonable cost principles[13] under section 1861(v) of the Act, based on the TH's ratio of Medicare usable organs to total usable organs. Medicare authorizes payment to designated OPOs for kidney acquisition costs, under reasonable cost

[9] H. Rep. 95–549 (July 29, 1977), section III.B.; S. Report 95–714 (March 22, 1978), section III.B.

[10] CMS Pub. 15–1, chapter 31 can be found at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929*) (Prior to the creation of chapter 31, the kidney acquisition policy was set forth in CMS Pub. 15–1, chapter 27, Outpatient Maintenance Dialysis Reimbursement).

[11] *https://oig.hhs.gov/oas/reports/region9/90800033.pdf*; *https://oig.hhs.gov/oas/reports/region9/90900087.pdf*; *https://oig.hhs.gov/oas/reports/region9/90500034A.pdf*; *https://oig.hhs.gov/oas/reports/region9/91102039.pdf*.

[12] *https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and*; *https://www.young.senate.gov/newsroom/press-releases/young-joins-finance-committee-members-to-probe-us-organ-transplant-system*; *https://www.congress.gov/117/chrg/CHRG-117hhrg44569/CHRG-117hhrg44569.pdf*.

[13] See 42 CFR 412.113(d); HCFA Ruling 87–1 (April 1987); CMS Ruling 1543–R (December 2006).

principles [14] in accordance with section 1861(v) of the Act, based on the OPO's ratio of Medicare usable kidneys to total usable kidneys (see section 1881(b)(2)(A) of the Act).

Histocompatibility laboratories provide laboratory services to ensure compatibility between donor organs and potential recipients in preparation for transplants. Section 1881(b)(2)(A) of the Act authorizes Medicare reimbursement for the cost incurred by a histocompatibility laboratory in accordance with sections 1861(v) or 1886 of the Act (if applicable). Histocompatibility laboratories are either independent or hospital-based. A histocompatibility laboratory is ''independent'' unless it is considered a department of the hospital and subject to control of the hospital.[15] Section 413.200(a) requires the reasonable costs of services furnished by histocompatibility laboratories be reimbursed in accordance with the principles contained in 42 CFR 413.60 and 413.64.

2. Organ Acquisition Payment Policy

We received approximately 400 timely pieces of correspondence regarding the proposals and policies discussed in this section of this final rule with comment period. Comment summaries and responses are included in each lettered section.

a. Terminology Notes and Proposed Definitions

(1) Use of Consistent Terminology

Throughout this final rule, we will use consistent terminology such as ''transplant hospital'' and ''transplant program.'' These terms have been defined in other CMS regulations at 42 CFR 482.70 as follows:

Transplant hospital means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

Transplant program means an organ-specific transplant program within a transplant hospital (as defined in this section).

The regulations in 42 CFR parts 412 and 413 had previously used ''transplantation center'' to mean a ''transplant program.'' Our PRM also uses ''certified transplant center'' to mean a TH, but we proposed to use consistent language in this rule to avoid confusion. In section X.B.2.m.(1). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we proposed conforming changes to some existing regulations to ensure that ''transplant hospital'' and ''transplant program'' are used consistently and as described in this section.

Comment: Some commenters expressed appreciation for CMS' use of consistent terminology.

Response: We appreciate the commenters' support. Throughout this final rule, we will refer to a hospital that has an approved organ-specific transplant program as a TH, and we will use ''transplant program'' to refer to the organ-specific program itself.

(2) Definitions

In addition to the proposals to use consistent terminology, in the preamble to the proposed rule we proposed to add specific definitions into the regulations by adding § 413.400, entitled ''Definitions,'' to new subpart L of 42 CFR, part 413. We also proposed to move all definitions in existing § 413.200(b) ''*Definitions*,'' to new § 413.400 to maintain this regulation with all other organ acquisition regulations in proposed new subpart L of part 413. Further, we proposed to revise some of the definitions proposed to be moved from § 413.200(b) to new § 413.400, as noted in the following discussion.

We received no comments on our proposal to move all definitions in existing § 413.200(b) to new § 413.400, thus we are finalizing our proposal as proposed.

For organ acquisition payment purposes, an ''organ'' means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine) as defined in 42 CFR 486.302. Effective October 1, 2004, organs also include pancreata procured for the purpose of acquiring pancreatic islet cells for transplantation into individuals who are participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial. Section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173) requires Medicare to pay for items and services that are reasonable and necessary routine patient care costs related to acquisition and delivery of pancreatic islet cells for transplantation into Medicare beneficiaries included in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial of islet cell transplants.

We proposed to codify our definition for ''organ'' in § 413.400, new subpart L. We noted that the proposed definition of organ is for Medicare organ acquisition payment purposes and differs from the definition set forth in 42 CFR 486.302 CfC for OPOs.

The CMS OPO CfCs final rule (85 FR 77898 published December 2, 2020) defines ''organ'' under 42 CFR 486.302, to mean a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine). The pancreas counts as an organ even if it is used for research or islet cell transplantation. The OPO CfC final rule (85 FR at 77947) describes the inclusion in the performance measures for OPO certification of pancreata used for research in the definition of organ as necessary in order to meet the statutory requirements of section 371(c) of the Public Health Service Act that provides that pancreata procured by an OPO and used for islet cell transplantation or research shall be counted for purposes of certification or recertification (85 FR 77902). However, for Medicare payment purposes, an organ procured for research is not counted as a Medicare organ in Medicare's share of organ acquisition costs, except where explicitly required by law. Therefore, in order to mitigate potential stakeholder confusion, we proposed a definition of ''organ'' for organ acquisition payment purposes that differs from the definition set forth in the OPO CfCs.

Comment: Several commenters requested CMS expand the definition of ''organ'' to include vascular composite allografts (VCAs), in alignment with the OPTN's definition of organ applicable to the OPTN under 42 CFR 121.2, and be included in organ counts for OPOs and THs so Medicare can calculate a share of acquisition costs for VCAs. A few commenters suggested the proposed definition of organ reimbursement be expanded to include other clinical trials and disease states.

Response: Our definition of organ in § 413.400 is for organ acquisition payment purposes that are outlined in the statute or adopted through the regulatory process to be paid outside of the IPPS. We have historically not included VCAs in the definition of organ for OPO CfCs because VCA transplantation is generally very localized and rarely performed.[16] According to OPTN data, in 2019, only approximately 15 such transplants occurred, the vast majority being the transplantation of a uterus (12 transplants). In 2020, there were five

[14] Id. Section 1138(b)(1)(F) of the Act; 42 CFR 413.1(a)(1)(ii)(A); 413.200(a).

[15] 43 FR 58371 (December 14, 1978).

[16] See 85 FR 77906. The OPTN database was accessed on July 11, 2020 and number of transplants for abdominal wall, head & neck (cranial facial), head & neck (scalp), GU: Penile, GU: Uterus, upper limb: Bilateral, upper limb: Unilateral, and VCA were counted for 2018 and 2019. In 2018, there were 11 transplants.

VCA transplants; in 2021 (through November 19, 2021), there were four VCA transplants.[17] Although it is not clear from the OPTN data whether these VCA transplant recipients were Medicare beneficiaries, inclusion of VCAs as organs would require a separate assessment of the impact throughout all CMS policies and regulations, and could lead to changes that would be beyond the scope of this rule. Although we may reconsider this issue in the future if VCA transplants become more common procedures, we are not expanding the definitions of ''organs'' to include VCAs for organ acquisition payment purposes in this final rule.

As noted, the proposed definition at § 413.400 specifically included in the definition of ''organ'' pancreata procured on or after October 1, 2004, for the purpose of acquiring pancreatic islet cells for transplantation into individuals who are participating in a National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) clinical trial. This rule implements Medicare's payment for the acquisition and delivery of pancreatic islet cells for transplantation into Medicare beneficiaries included in a NIDDK clinical trial of islet cell transplants required by section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173). Section 733 requires routine costs, transplantation and appropriate related items and services for the acquisition and delivery of the pancreatic islet cell transplantation for Medicare beneficiaries who are participating in a clinical investigation of pancreatic islet cell transplantation. In light of this specific statutory requirement, we believe it would be inappropriate to expand the definition of organ in § 413.400 to include other clinical trials and disease states as commenters suggested.

After consideration of public comments, we are finalizing our definition of ''organ'' for acquisition payment purposes, as proposed, at § 413.400, in new subpart L, with modifications based on comments received to clarify the definition of pancreata for organ acquisition payment purposes, by adding the public law citation to the definition. In this regard, we are finalizing that an organ, for organ acquisition payment purposes, includes pancreata procured on or after October 1, 2004, for the purpose of acquiring pancreatic islet cells for transplantation into individuals who are participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial in accordance with section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

In the proposed rule, we proposed to include the definition of Organ Procurement Organization (OPO) as it currently exists in § 413.200(b). As defined in 42 CFR 486.302, an OPO means an organization that performs or coordinates the procurement, preservation, and transport of organs and maintains a system for locating prospective recipients for available organs. An OPO can be a HOPO or an independent OPO. An OPO is ''independent'' unless it is considered a department of the hospital and subject to control of the hospital.

Comment: Several commenters also requested we amend the proposed definition of ''OPO'' to reflect that the OPTN, and not the OPO, maintains the system for identifying and locating prospective beneficiaries for available organs.

Response: We appreciate the commenters' suggestion; however, we respectfully disagree with modifying the definition as commenters suggest. OPOs do have a system for locating prospective beneficiaries for available organs. We do not believe our definition will cause confusion with respect to the separate functions of the OPTN. After consideration of the public comments we received, we are finalizing our proposed definition of ''OPO'' as proposed.

Additionally, we proposed to codify the definition of a hospital-based organ procurement organization (HOPO) as an OPO that is considered a department of the TH and reports organ acquisition costs it incurs on the TH's Medicare cost report (MCR).[18] The proposed definition is consistent with the description of HOPO in the PRM, and is commonly known in the organ acquisition and transplant community. We proposed to codify our proposed definition in § 413.400, new subpart L. As of March 12, 2021, there are 7 HOPOs in operation.[19]

We also proposed that a transplant hospital/HOPO (TH/HOPO) refers to a transplant hospital, or a transplant hospital that operates a HOPO (as defined previously in this section) and performs organ procurement activities as one entity reported on the transplant hospital's MCR. We proposed to codify our proposed definition in § 413.400 new subpart L.

Comment: A commenter recommended the definition of HOPO should be separate from the definition of TH/HOPO due to differences in various organ acquisition reporting and operational activity between a HOPO and a transplant program.

Response: We agree that there are differences in various organ acquisition reporting and operational activity between a HOPO and a transplant program. We note that in the proposed rule, we proposed a separate definition for ''HOPO.'' However, we also proposed a definition of TH/HOPO, to indicate that a TH/HOPO means a transplant hospital and a transplant hospital with a hospital based OPO, which is an OPO owned and operated by the hospital. In this context, the HOPO is reimbursed through the transplant hospital's cost report as a department of the hospital and does not file a cost report separately from the transplant hospital nor is it reimbursed separately. We are codifying our proposed definitions of HOPO and TH/HOPO, as proposed, at § 413.400, in new subpart L.

In the proposed rule, we also proposed to revise the terminology ''freestanding'' as it currently exists in 42 CFR 413.200(b) in relation to OPOs, to be ''independent OPO (IOPO)'' because this terminology is more widely used in the industry. We also proposed to revise the IOPO definition by adding a third distinguishing factor. The proposed definition for an IOPO will mean an OPO that files a MCR separate from a hospital and meets all of the following: (1) Is not subject to the control of a hospital with respect to the hiring, firing, training, and paying of employees; (2) is not considered as a department of a hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance); and (3) reports organ acquisition costs it incurs on the IOPO MCR.[20] In the preamble to the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to clarify that an IOPO that wishes to have the cost of its pre-transplant services reimbursed under Medicare must agree to certain requirements specified in 42 CFR 413.200(c). If an IOPO operates a histocompatibility laboratory, the costs of its histocompatibility laboratory are included on the IOPO's MCR. We received no comments on this proposal;

[17] *https://insights.unos.org/OPTN-metrics/.*

[18] Hospital and Health Care Complex Cost Report, currently Form CMS–2552, OMB No. 0938–0050.

[19] Information available at *https://optn.transplant.hrsa.gov/members/*; accessed March 12, 2021.

[20] Organ Procurement Organizations and Histocompatibility Laboratory, currently Form CMS–216, OMB. No. 0938–0102.

therefore, we are codifying our proposed definition of IOPO, as proposed, at § 413.400, in new subpart L.

In the FY 2022 IPPS/LTCH PPS proposed rule, we stated that a histocompatibility laboratory performs laboratory services to determine the degree of histocompatibility between donor organs and potential recipients. We also proposed to include a definition of ''histocompatibility laboratory'' as it currently exists in § 413.200(b) with a technical correction. We proposed to make a technical correction to the cross-reference to § 413.2171(d) because this regulation citation is no longer correct. We proposed that ''histocompatibility laboratory'' means a laboratory meeting the requirements set forth in 42 CFR 493.1227 and providing the services for the acquisition of kidneys or other organs for transplantation. We received no comments on this proposal; therefore, we are finalizing our proposed definition of histocompatibility laboratory, as proposed, at § 413.400, in new subpart L.

We proposed that standard acquisition charge (SAC) means a charge as defined in proposed new § 413.404 in section II.C.2.c. of this final rule with comment period. We received no comments on this proposal; therefore, we are codifying our proposed definition of SAC, as proposed, at § 413.400, in new subpart L.

We also proposed to add the definitions for ''transplant hospital'' and ''transplant program'' that currently exist in 42 CFR 482.70 in § 413.400, to new subpart L.

Comment: A few commenters supported our clarification of transplant hospital and transplant program.

Response: We thank the commenters for their support. We are codifying our proposed definitions for ''transplant hospital'' and ''transplant program,'' as proposed, at § 413.400, in new subpart L.

b. Provisions Related to Organ Acquisition Costs

(1) Proposed Items and Services Considered Organ Acquisition Costs

In this final rule with comment period, we are adding § 413.402(a) to new subpart L to specify that costs incurred in the acquisition of organs from a living donor or a cadaveric donor by the hospital or by an OPO, as appropriate, are organ acquisition costs. To make necessary policy revisions and clarifications of acquisition costs for kidneys as well as for non-renal organs, in the proposed rule we proposed to revise § 412.100(b), by removing the list of organ acquisition costs found in that paragraph and re-codifying them with some revisions by adding § 413.402(b) to new subpart L.

We proposed to codify at proposed § 413.402(b) that the costs of acquiring organs (kidneys and non-renal organs) covered by Medicare Part A are: (1) Tissue typing, including tissue typing furnished by independent laboratories; (2) donor and beneficiary evaluation; (3) other costs associated with excising organs, such as general routine and special care services provided to the donor; (4) operating room and other inpatient ancillary services applicable to the donor; (5) preservation and perfusion costs; (6) OPTN registration fees; (7) surgeons' fees for excising cadaveric organs (currently limited to $1,250 for kidneys); (8) transportation of the excised organ to the TH; (9) costs of organs acquired from other hospitals or OPOs; (10) hospital costs normally classified as outpatient costs applicable to organ excisions (services include donor and recipient tissue typing, work-up, and related services furnished prior to admission); (11) costs of services applicable to organ excisions which are rendered by residents and interns not in approved teaching programs; and (12) all pre-admission services applicable to organ excisions, such as laboratory, electroencephalography, surgeons' fees for cadaveric excisions, and the costs of physicians' services.

We proposed to apply the existing elements of kidney acquisition costs found in § 412.100(b) to all organs, with clarifying revisions as described. These items and services are currently specified in § 412.100(b) (for kidneys only) and also discussed in sections 3101, 3102, and 3103 of the PRM. We proposed to revise § 412.100(b) to reference that kidney acquisition costs are specified in new § 413.402(b) of this chapter.

We proposed to add § 413.402(b)(6) to new subpart L to include the costs for the OPTN registration of a beneficiary for a kidney transplant as specified in § 412.100(b)(6) and also include the costs for registration of a beneficiary for a non-renal transplant. The OPTN registration fee is assessed for all transplant candidates placed on the OPTN waiting list.[21] We proposed to limit these registration fees to the OPTN registration fee. Reasonable cost principles, as set forth in section 1861(v) of the Act and as specified in 42 CFR 413.1(b) and 413.9, do not permit Medicare to pay for duplicate services. In the proposed rule, we asserted that any registration fee outside of the OPTN registration fee would be considered unnecessary and duplicative under reasonable cost principles for Medicare organ acquisition costs.

Payment mechanisms for certain kidney acquisition costs differ depending on whether the donor is living or is cadaveric. Our provision will codify that surgeon fees are included as kidney acquisition costs paid through the Medicare cost report only when the kidney excision occurs with a cadaveric donor. When a living donor enters the hospital for the actual kidney excision—and the recipient is a Medicare beneficiary—surgeon fees for excising the kidney are still considered kidney acquisition costs, but are not included as kidney acquisition costs on the cost report or paid through the cost report. Instead, the surgeon bills these surgeon fees to Medicare Part B using the transplant recipient's Medicare Beneficiary Identifier (MBI), and Medicare pays for living kidney donor surgeon fees through the claims processing system. Congress enacted section 1881(d) of the Act in 1978, which (in part) entitled living donors to benefits under Medicare Part B with respect to the kidney donation, as if the donor were eligible for Medicare, and allowed the Secretary to prescribe in regulation how that would occur. CMS regulations at 42 CFR 410.55 and 410.163,[22] require Medicare Part B to pay for medical and other health services furnished in connection with a kidney donation if the kidney is intended for a Medicare beneficiary with ESRD and without deductibles or co-insurance. As such, our proposed codification of Part A kidney acquisition costs related to donor surgeon fees only focuses on surgeons' fees for cadaveric excisions.

Section 371(b)(3)(F) of the PHS Act, 42 U.S.C. 273(b)(3)(F), requires that OPOs provide or arrange for the transportation of donated organs to transplant centers. We proposed to codify our longstanding policy in PRM section 3101 that Medicare covers the transportation of donated organs as an organ acquisition cost as authorized by section 371(b)(3)(F) of Public Health Service Act.

We proposed to add § 413.402(b) to new subpart L to specify the acquisition costs given at § 412.100(b) of this chapter, with minor clarifying revisions,

[21] The hospital CoPs at 42 CFR 482.45(b)(1) require each TH to be a member of the OPTN and abide by its rules, which for THs include registering potential transplant recipients on the OPTN registry as described in section 1.2.D of the OPTN Bylaws, available at *https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf.*

[22] 51 FR 41332.

and to revise § 412.100(b) to cross-reference § 413.402(b). We also proposed to make additional revisions, technical corrections and conforming changes to § 412.100 in sections II.C.2.b.(1). and II.C.2.m.(2). of this final rule with comment period.

Finally, we have received inquiries over the years from various stakeholders about whether costs resulting from services to living kidney donors with complications are organ acquisition costs. We proposed to codify that policy in § 413.402(c) in new subpart L, to provide greater clarity to stakeholders. We discuss details of our policy and proposed codification related to living donor complications in section II.C.2.e.(4). of this final rule with comment period.

Comment: Many commenters appreciated our proposals to codify policy and to locate organ acquisition policies in a common location in the regulations. However, several commenters were concerned that our proposal to limit registry fees to the OPTN fee at proposed at § 413.402(b)(6) would shift costs of registry fees to transplant hospitals for living donors or donors participating in kidney-paired donations, would discourage living donor transplants, and could jeopardize health equity, particularly for kidney-only programs. Commenters requested that CMS not limit registry fees to the OPTN fee only and cited a 2014 letter from CMS that stated that transplant hospitals can engage in contracts with third-parties that provide services to facilitate transplantation and place the costs of those services on their cost reports. A commenter supported CMS not covering the fee charged by the current contractor that operates the OPTN, while other commenters supported CMS' covering that fee. A commenter objected to CMS referring to the OPTN contractor fee services as ''duplicative'' of the OPTN registry and described the services the contractor performs to facilitate and support organ transplantation.

Response: We appreciate commenters' support for our proposals to codify organ acquisition cost policies in one location in the Code of Federal Regulations and thank commenters for sharing their concerns about the proposed registry fee costs. We agree that the OPTN contractor and other registries can provide valuable services that support and encourage transplantation. After further researching registry fee information provided in the comments, we are clarifying that we cover as registry fees only the reasonable fees for actually registering a potential recipient for an organ transplant.

We also agree with commenters that the services other registries provide may differ from those provided by the OPTN. For example, we agree with commenters that third-party registries can provide services beyond those of the OPTN to facilitate living organ donation, particularly related to paired kidney donation, and increase a potential transplant recipient's ability to receive a living donor transplant. As such, we do not believe that all additional registry fees would be ''duplicative'' of the OPTN services. We believe covering the reasonable and necessary costs of registry fees that are not duplicative will support transplantation. Therefore, we are finalizing our proposal with modifications, so that Medicare covers as organ acquisition costs at § 413.402(b)(6) the OPTN registration fee, and the reasonable and necessary cost of other fees, such as the registration fees for a kidney paired exchange, to register candidates for organ or kidney transplants. These allowable registry fees must support or promote organ transplantation and must not be duplicative in nature. We will monitor the registry fees reported and may refine our policy if needed in future rulemaking.

Comment: Many commenters disagreed with our proposal at § 413.402(b)(8) that organ acquisition costs include costs to transport the excised organ to the transplant hospital, but excludes costs for transporting the cadaveric donor. Some commenters suggested that the exclusion of transportation costs for the cadaveric donor was a new policy proposal and believed that the proposal was eliminating costs for transportation of the cadaveric donor from the donor hospital to an OPO. Some commenters opined that the proposal would impede operations of OPOs that may operate organ recovery centers. Several commenters cited 42 U.S.C. 273(b)(3)(F), (requiring OPOs to provide or arrange for transportation of donated organs to transplant centers), and asserted that this section does not prohibit transportation of the donor (as opposed to individual organs) when the transportation is for the purpose of transplantation. A few commenters suggested that CMS permit transportation of the cadaveric donor to an off-site recovery facility when it could be proven that the overall costs of acquisition would be lower.

Commenters raised three other scenarios where a cadaveric donor may require transportation to another hospital: (1) When the donor hospital's protocol does not permit organ excision when cardiac death has occurred; (2) when clinical outcomes could be compromised because the donor hospital is not geographically located within reasonable proximity to needed transportation infrastructure, such as an airport, when the organ must be flown to the intended recipient; and (3) where the donor hospital does not have the capacity at that time to accommodate organ procurement. The commenters opined that in these situations, transporting the donor avoided the loss of transplantable organs or increased the likelihood of the organs' viability. Another commenter requested clarification as to whether it was permissible for the donor to be moved from the donor hospital to the transplant hospital. A commenter requested that the proposed codification of transportation costs remain as it was written in § 412.100(b).

Finally, a commenter sought clarification of transportation costs for transporting non-renal organs. The commenter noted that the non-renal organs travel with the surgeon on the plane, so there is no incremental cost for transportation of the organ. The commenter stated that it would be administratively burdensome for the OPO and the transplant hospital to apportion the transportation costs and requested exclusion of the non-renal transportation in this situation, as there is no ''cost'' associated with the organ transportation.

Response: The current Medicare organ acquisition payment policy does not include transportation costs for a cadaveric donor. However, we agree with commenters that 42 U.S.C. 273(b)(3)(F) does not prohibit Medicare from covering transportation of the cadaveric donor. We appreciate the scenarios commenters provided relating to transportation of a cadaveric donor and believe that broadening coverage of transportation costs would more strongly support organ procurement and transplantation. We also agree with commenters that it would be reasonable to allow transportation costs of a cadaveric donor when that donor is transported to avoid loss of potentially transplantable organs, or to preserve clinical outcomes.

The lack of clarity of the existing payment policy was evident in some of the comments, which is why we are being more specific in our codification of the payment policy regarding transportation costs. For the reasons noted in this section of this final rule with comment period, we are finalizing our proposed codification at § 413.402(b)(8) with modifications in

response to public comments, to cover as an organ acquisition cost transportation of the excised organ to the transplant hospital, and of the cadaveric donor to procure organs when it is necessary to preserve clinical outcomes or to avoid loss of potentially transplantable organs. We believe this modification to our current policy is responsive to commenters' concerns, and will support organ procurement, address potential disparities in rural areas, and improve clinical outcomes.

Regarding the transportation of non-renal organs, the commenter described a scenario in which the commenter believed there is no additional cost incurred for organ transportation when the transplant team travels to procure and retrieve the organ. In this scenario we agree that there is not a transportation cost incurred for the organ and therefore no need to apportion the travel costs. However, under the general requirements at §§ 413.20 and 413.24 to maintain records for items submitted on the Medicare cost report for proper cost finding and payment, the OPO and transplant hospital would have to maintain accurate records for the number of organs procured without transportation costs and the number of organs procured with transportation costs in order to properly allocate overhead costs. We note that when an OPO does not incur transportation costs for all organs, the transportation costs for kidneys would be reduced from the accumulated costs statistic in order to equitably allocate overhead costs.

Comment: Commenters requested clarification of whether transportation of recovery staff, including donor family support staff, would be allowable organ acquisition costs. A different commenter referred to procuring multiple organs which had no incremental cost for transportation beyond the charter flight travel costs for the procurement team. This commenter stated that the OPO has no control over the cost of charter transportation, stating it would require contracts with multiple transportation providers that may not be known to the OPO until the transportation has been arranged.

Response: We differentiate ''transportation'', which refers to the organ or the cadaveric donor, from ''travel,'' which includes travel costs of physicians or other practitioners that recover organs under contract or arrangement with the OPO, as well as recovery personnel if necessary, either from its own staff or under contract or arrangement, to ensure that all usable organs are recovered in a manner that, to the extent possible, preserves them for transplantation. These reasonable travel costs are allowable organ acquisition costs under § 413.402(b)(9) as they are costs of organs acquired from other hospitals or OPOs. If multiple organs are procured, the travel costs for the procurement team should be apportioned equitably to all organs.

We are concerned by the commenter's statement that the OPO ''has no control'' over the cost of air charters, and we remind stakeholders that reasonable cost principles apply to all organ acquisition costs. Reasonable cost includes all necessary and proper costs incurred in furnishing the services, as defined in 42 CFR 413.9. For example, in this scenario an OPO might have contracts with multiple transportation providers and could negotiate a reasonable price for air charters.

Comment: Several commenters were concerned that the specific language we used in proposing to codify allowable organ acquisition costs for proposed § 413.402(b)(3) (other costs associated with excising organs, such as general routine and special care services) and proposed § 413.402(b)(4) (operating room and other inpatient ancillary services) as set forth in section X.B.2.b.(1). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, does not match the language that currently exists in the relevant sections of Chapter 31 of the Provider Reimbursement Manual (PRM) or may be subject to misinterpretation by a MAC auditor to apply only to living donors. Commenters requested clarification of whether the organ acquisition costs incurred for these services will be covered for both living and cadaveric donors.

Response: We agree with commenters that other costs associated with excising organs, such as general routine and special care services provided to the donor specified in proposed § 413.402(b)(3) and operating room and other inpatient ancillary services applicable to the donor in proposed § 413.402(b)(4) should be clarified to specify that they apply to both living and cadaveric donors. The commenters' suggestions are consistent with the existing policy and could avoid misinterpretation of the policy. Additionally, in reviewing the language, we realized that ''special care services'' was not clear, and we added language to give two examples (intensive care unit or critical care unit services) so providers could better understand.

Therefore, in response to commenters and to clarify language, we are finalizing our proposed regulation text with modifications to clarify the regulation text at § 413.402(b)(3) and § 413.402(b)(4). The final regulation at § 413.402(b)(3) now specifies that other costs associated with excising organs, such as general routine and special care services (for example, intensive care unit or critical care unit services), provided to the living or cadaveric donor are organ acquisition costs. The final regulation at § 413.402(b)(4) now specifies that operating room and other inpatient ancillary services applicable to the living or cadaveric donor are organ acquisition costs. After our regulations are effective, we will make conforming changes to the manual.

Comment: A commenter requested that CMS consider the full spectrum of ''uncompensated costs'' related to organ procurement and transplantation, including overhead and administrative costs.

Response: Overhead and administrative costs that may be allowable are allocated to allowable cost centers, including to organ acquisition cost centers. See 42 CFR 413.24(d), and also the cost reporting instructions for hospitals and for OPOs regarding how general and administrative (that is, overhead) costs are allocated (for hospitals, PRM 15–2, chapter 40, cost reporting instructions § 4020, and for OPOs PRM 15–2, chapter 33, cost reporting instructions § 3311, available online at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935*). We have clarified the regulation text at § 413.402(a) to specify that there are administrative and general costs that may be allowable and included on the cost report for an OPO or TH/HOPO.

Comment: A commenter questioned whether living donor specimen storage, recently required by the OPTN, will be covered as an organ acquisition cost.

Response: Prior to the OPTN implementing policy changes to align with the 2020 Public Health Services guidelines, hospitals and OPOs should have been following the Public Health Services guidelines. This cost associated with this specimen storage should be treated similar to all other specimen storage and not included as an organ acquisition cost.

Comment: A commenter requested that CMS consider ''uncompensated'' costs related to organ procurement and transplantation for pathologists and other specialists contracted under third party contracts that are indispensable to the organ recovery and transplantation process.

Response: Regarding the costs of pathologists and other specialists under third-party contracts, we are unclear what commenters are referring to, and

without more context, are unable to modify the final rule to address this comment.

Comment: Many commenters believed that some of our proposals were intended to be retroactive rules to codify existing organ acquisition payment policy. Other commenters believed that the rules would be prospective from the effective date of the final rule and that the agency did not intend to establish retroactive rules.

Response: We did not propose to establish retroactive rules under section 1871(e)(1)(A) of the Act. Our final rules will generally be effective upon the effective date of the final rule. This FY 2022 IPPS final rule with comment period will be effective on the effective date specified in the **DATES** section of this final rule with comment period, unless a later date is specified. We note that a limited number of the final regulations expressly include the effective date of earlier statutes that have already established substantive standards. Specifically, the final rule at § 413.406 includes an effective date of October 1, 2004, from section 733 the Medicare Modernization Act of 2003, as it relates to Medicare coverage of islet cell transplants. This is not a new policy change nor would it now result in a substantive change, as the statute was already effective.

(2) Cost Reporting, Billing, and Payment of Organ Acquisition Costs

Both THs and OPOs can acquire organs for transplantation; therefore, both THs and OPOs can have organ acquisition costs. A TH can acquire organs from either a cadaveric donor or a living donor, while OPOs acquire organs from cadaveric donors. In accordance with requirements at § 413.24(f), at the end of its fiscal year a TH/HOPO files an annual hospital cost report (currently Form CMS–2552) [23] and an IOPO files an annual OPO/histocompatibility cost report (currently Form CMS–216).[24] Organ acquisition costs incurred by a TH/HOPO are included on the appropriate organ acquisition cost center on its hospital MCR. Organ acquisition costs incurred by an IOPO (or by a histocompatibility laboratory, as authorized in section 1881(b)(2)(A) of the Act and discussed in section II.C.2.d.(3). of this final rule with comment period) are included in the appropriate organ acquisition cost center on its MCR.

Currently, Medicare pays THs prospective payment amounts based on a DRG for the actual organ transplant; Medicare also reimburses THs for reasonable costs associated with acquiring organs for transplantation into Medicare beneficiaries (§ 412.113(d)). CMS excludes from the prospective payment amounts inpatient hospital organ acquisition costs for hearts, kidneys, livers, lungs, pancreas, and intestines (or multivisceral organs) incurred by approved THs, as specified in § 412.2(e)(4). Medicare makes payment for organ acquisition costs incurred by hospitals with approved transplantation programs on a reasonable cost basis, as specified in § 412.113(d), and in accordance with the principles of reasonable cost as set forth in section 1861(v) of the Act and in 42 CFR 413.1 and 413.9.

Currently, when the TH cost report is settled, the Medicare contractor calculates the Medicare organ acquisition costs by multiplying the total of all allowable organ acquisition costs by the ratio of Medicare usable organs to total usable organs, for each organ type. The contractor reconciles the TH's Medicare organ acquisition costs by comparing the total interim payment amounts paid for organ acquisition costs under § 413.64(f) to the total actual Medicare organ acquisition costs, and either pays amounts owed or collects from the TH any overpayment.

The statute at section 1881(b)(2)(A) of Act authorizes Medicare to pay THs for services provided by OPOs for kidney acquisition. Medicare does not directly reimburse OPOs as these services are not covered until the transplant occurs at the TH. OPOs receive an interim payment based on their kidney SAC which is paid directly to them by the TH that receives the kidney procured. Medicare pays IOPOs for kidney acquisition indirectly, through the reconciliation of actual costs incurred for kidney acquisition to actual kidney SAC payments received, as part of cost report settlement in accordance with § 413.200(e)(2), to ensure that the Medicare Program is paying its appropriate share. There is no explicit requirement for Medicare to pay IOPOs for non-renal organs in the same way; we do not currently reconcile and settle IOPO non-renal organ acquisition costs. Similar to kidney acquisition costs, IOPOs are paid an interim rate (SAC) directly by the TH (or other IOPO) which receives the non-renal organs the IOPO procures. Kidney and non-renal SACs are discussed in more detail in section II.C.2.c. of this final rule with comment period.

(3) Services Not Considered Organ Acquisition Costs

Medicare does not pay for certain costs incurred by OPOs, in accordance with section 1861(v)(1)(A) of the Act, and in the proposed rule we proposed to establish rules identifying those specific items. These activities or services include incurred costs found to be unreasonable or unnecessary in the efficient delivery of health care services, and are not limited to: [25]

- Burial and funeral expenses for the cadaveric donor, including transportation of the cadaveric donor before and after excision for funeral services or for burial (burials and funerals are not costs of acquiring organs and are not mentioned in section 371(b)(3) of the PHS Act (42 U.S.C. 273(b)(3)), which lists a number of activities or services that OPOs perform); [26]
- Costs associated with the transportation of a living donor [27] (there are programs outside of Medicare that may pay for transportation costs for living donors); [28]
- Costs incurred prior to a potential cadaveric donor being declared dead;
- Fees or in-center payments for donor referrals (all hospitals are required to timely notify OPOs of imminent deaths; [29] PRM 15–2, chapter 40, section 4013 stipulates that, ''No amounts or fees paid to a donor, their estate, heirs, or assigns in exchange for an organ or for the right to remove or transplant an organ are included in organ acquisition costs.'');
- Costs associated with OPO sponsored seminars where continuing education credits are given [30] except when the attendee is an OPO staff member; and
- Certain costs incurred for administrator's duties associated with professional organizations (when these costs are not reasonable).

Comment: A few commenters encouraged us to allow OPO-sponsored seminars with continuing education credits as allowable organ acquisition costs, noting that it would improve and advance the organ transplant system. Another commenter questioned whether

[23] OMB No. 0938–0050, expires March 31, 2022.

[24] OMB No. 0938–0102, expires November 30, 2024.

[25] PRM 15–1, ch 31, § 3108.C.

[26] 42 U.S.C. 273(b)(3).

[27] 42 U.S.C. 273(b)(3)(F). This section requires OPOs to provide or arrange for the transportation of donated organs to transplant centers.

[28] 85 FR 59438, September 22, 2020; see also the National Living Donor Assistance Center website at *https://www.livingdonorassistance.org/About-Us/Mission-Background.*

[29] 42 CFR 482.45.

[30] See CMS Pub. 15–1, chapter 4 for more information regarding allowable costs of educational activities.

seminars without continuing education credits would be covered.

Response: The reasonable cost of an OPO-sponsored seminar that provides continuing education credits, may be an allowable administrative and general cost (included as organ acquisition costs) limited to the OPO staff (as described at § 486.326(b)) if the seminar is related to patient care and meets the requirements at § 413.9. The reasonable cost of an OPO-sponsored seminar that provides continuing education credits to attendees who are not on the OPO's staff is not an allowable organ acquisition cost as these costs are absorbed by the attendee or their employer and do not benefit the OPO.

The reasonable cost of an OPO-sponsored seminar that does not provide continuing education credits, regardless of whether it is provided to the OPO staff, may be an allowable administrative and general cost to the OPO if it relates to patient care and meets the requirements at § 413.9.

OPO-sponsored seminar costs are the direct costs associated with providing the seminar such as retaining speakers, supplies, meeting room fees, and meals (excluding alcohol) where necessary.

Based on comments received, we are codifying at § 413.402(d) that organ acquisition costs do not include OPO-sponsored seminar costs associated with attendees who are not on the OPO's staff and receiving continuing education credits.

Comment: A commenter requested that CMS clarify which Administrator's duties associated with professional organizations are not covered.

Response: Regarding certain costs incurred for administrator's duties associated with professional organizations, § 413.9(a) allows Medicare coverage of costs that are reasonable and related to the care of beneficiaries, as discussed in the previous comment response. The reasonable cost of membership in professional organizations would be allowable if the function and purpose of the organization can be reasonably related to the development and operation of patient care facilities and programs, or the rendering of patient care services (see PRM 15–1, § 2138). Membership costs and costs related to the organization's meetings and conferences are allowable as described in § 2138.1. However, § 2138.4 notes that the Medicare Program will look to comparable providers as well as to the justification by the individual provider in determining the reasonableness of the claimed costs related to memberships. Costs to the Medicare Program for individuals serving in administrative roles for professional organizations may be more than the costs for an ordinary member of a professional organization, as those in administrative roles for the organization may have to attend additional meetings, etc. as part of their duties. However, professional organization costs for those in administrative roles that are unreasonable would not be allowable. An example of unreasonable costs would be if an individual in an administrative role for a professional organization attended a meeting held at a luxury resort, where lodging costs were substantially more expensive than usual (see 42 CFR 413.9(c)(3)). We have revised the text in the preamble at II.C.2.b.(3) of this final rule with comment period to explain the rationale to exclude certain administrator duty costs that are not reasonable. As discussed at the end of section II.C.2.b.(3). of this final rule with comment period, after considering public comments, we have codified costs that are not related to organ acquisition at § 413.402(d).

Comment: Several commenters stated that CMS should revise the preamble language pertaining to costs not covered by Medicare that reads, ''Costs incurred prior to a potential donor being declared brain dead (healthcare costs incurred prior to declaration of death are the responsibility of the potential donor's health insurance).'' Commenters noted that some donors are declared dead based on cardiac or circulatory death, and the phrasing should not be limited to brain death only. Finally, we received several comments related to covering costs prior to declaration of death.

Response: We agree with commenters and have corrected the preamble text in this final rule in response to these comments. We agree with the commenters who stated that our language in section X.B.2.b.(3). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule about costs incurred prior to a potential donor ''being declared brain dead'' should be revised to read ''being declared dead'', to include those donors who die from cardiac death. Finally, the summary of comments and responses related to covering costs prior to declaration of death are in section II.C.2.l. of this final rule with comment period.

Comment: A commenter supported the continued exclusion from Medicare coverage of the transportation of the cadaveric donor for burials or funerals; another commenter challenged part of our rationale for non-coverage, writing that section 371(b)(3) of the PHS Act does not represent an all-inclusive list of allowable services for OPOs.

Response: We thank the commenter for supporting our policy. Regarding our rationale for non-coverage of transportation of cadaveric donors for funeral services or for burial, our policies regarding items and services that are covered as organ acquisition costs are based, in general, on whether the item or service is related to acquiring organs for transplantation. We agree with the commenter who stated that section 371(b)(3) of the PHS Act does not specify every item or service covered as an organ acquisition cost. When an item is not explicitly cited, we must determine if it meets the general principle of being related to acquiring organs for transplantation. Costs of transporting a donor for burial or for a funeral are not cited in the PHS Act as covered costs, but are also not costs of acquiring organs for transplantation. Therefore, we are maintaining our policy that transporting a deceased donor for a funeral or for burial is not related to the acquisition of organs, and is not an allowable cost.

In summary, effective for cost reporting periods beginning on or after the effective date of this final rule with comment period, we are finalizing the provisions made in section II.C.2.b. of this final rule with comment period as proposed, except for the following modifications:

- In § 413.402(a) to specify that there are administrative and general costs that may be allowable and included on the cost report for an OPO or TH/HOPO.
- In § 413.402(b)(3) to specify that organ acquisition costs include other costs associated with excising organs, such as general routine and special care services (for example, intensive care unit or critical care unit services), provided to the living or cadaveric donor.
- In § 413.402(b)(4) to specify that organ acquisition costs include operating room and other inpatient ancillary services applicable to the living or cadaveric donor.
- In § 413.402(b)(5) to clarify the regulation by adding the word ''organ'' so we are specifying that organ preservation and perfusion costs are organ acquisition costs.
- In § 413.402(b)(6) to specify that organ acquisition costs include Organ Procurement and Transplantation Network registration fees and the reasonable and necessary cost of other fees to register candidates for organ transplants. These allowable registry fees must support or promote organ transplantation and must not be duplicative in nature.
- In § 413.402(b)(8) to specify that organ acquisition costs include

transportation of the excised organ to the transplant hospital; and of the cadaveric donor to procure organs when it is necessary to improve clinical outcomes or to avoid loss of potentially transplantable organs.

- In § 413.402(b)(12) to remove the reference to surgeons' fees for cadaveric excisions as it is duplicative of § 413.402(b)(7).
- In section II.C.2.b.(3). of this final rule with comment period, to change ''declared brain dead'' to read ''declared dead''.
- In section II.C.2.b.(3). of this final rule with comment period, to indicate that the cost of OPO-sponsored seminars that provide continuing education credits is not covered unless the attendee is an OPO staff member.
- In section II.C.2.b.(3). of this final rule with comment period, to revise the rationale for not covering certain costs of administrator duties for those in professional organizations to indicate that costs that are unreasonable would be excluded.

While we did not propose to codify the items and services not covered as OPO organ acquisition costs described in the proposed rule, after consideration of the public comments we received seeking clarification or suggesting changes, we believe it is prudent to codify the list of examples of items and services not considered to be organ acquisition costs. As such, in this final rule we are codifying at § 413.402(d), costs not related to organ acquisition in which we specify that items or services that are not related to acquiring an organ for transplantation, or that are not reasonable under section 1861(v)(1)(A) of the Act, or that are non-allowable administrative and general costs, or that are not related to patient care under 42 CFR 413.9 of the regulations are not considered organ acquisition costs. Examples of items or services that are not organ acquisition costs include, but are not limited to: Donor burial and funeral expenses, transportation of the cadaveric donor after organ procurement for funeral services or for burial; transportation costs for a living donor; fees or in-center payments for donor referrals; costs associated with and incurred for OPO-sponsored seminars where continuing education credits are given and where the attendee is not on the OPO's staff (as described at § 486.326(b)); and unreasonable costs incurred for administrator's duties associated with professional organizations.

c. Provisions Related to Standard Acquisition Charges

Because a number of the SAC comments received addressed proposals in multiple subsections, the comment summaries and our responses are at the end of section II.C.2.c. of this final rule with comment period.

(1) General

We proposed to clarify and codify Medicare's policy regarding TH/HOPO SACs in new subpart L, § 413.404, as discussed herein. The IL 74–23, issued in July 1974, set forth the policies and procedures for a hospital to develop standard kidney acquisition charges for the acquisition of kidneys from living or cadaveric donors. Over the years, as Medicare added coverage for non-renal transplants, Medicare used these same policies and procedures for THs to develop living and cadaveric SACs for non-renal organs and OPOs to develop cadaveric SACs for non-renal organs.

A SAC for an organ is an amount that represents the estimated costs a TH or an OPO expects to incur to acquire an organ. The SAC does not represent the actual acquisition cost for an individual organ. Instead, the SAC generally represents the average of the total organ acquisition costs associated with procuring either cadaveric donor organs or living donor organs, by organ type.

A TH or OPO cannot bill Medicare directly for the cost of procuring an organ because procuring an organ is not a covered service when performed independent of a Medicare covered transplant, and it is not always known at the time of organ procurement whether the potential recipient is a Medicare beneficiary. However, the reasonable costs of procuring an organ are reimbursable when billed in connection with a Medicare covered transplant. When a TH bills Medicare for the transplant, it bills the DRG charge for the organ transplant and uses its SAC to bill Medicare for the procured organ (currently using revenue code 081X).[31] THs develop categories of living or cadaveric SACs, by organ type (for example, heart, liver or lung). When a TH/HOPO or IOPO furnishes an organ to another TH/HOPO or IOPO, we proposed that it must bill the receiving TH/HOPO or IOPO its SAC. We proposed to codify these provisions pertaining to SACs at proposed new § 413.404(a) in new subpart L.

[31] Medicare internet Only Manual 100–04, Medicare Claims Processing Manual, Chapter 3, Section 90, available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf.*

(2) Transplant Hospitals and HOPOs

We proposed to codify provisions pertaining to SACs for TH/HOPOs for living and cadaveric donors at proposed new § 413.404(b) in new subpart L, as described in this section.

(a) Living Donor Standard Acquisition Charge

We proposed to codify Medicare's longstanding policy regarding a TH's standard acquisition charges for living donors at proposed new § 413.404(b)(3)(i) in new subpart L as discussed herein, because these policies remain relevant. THs must develop a SAC for living donor organs, by organ type (for example kidney, liver, or lung). THs/HOPOs must develop a SAC for cadaveric organs, by organ type. The living donor SAC is an average organ acquisition cost the transplant hospital incurs to procure an organ from a living donor. As medicine and transplantation have advanced, Medicare now covers transplants into beneficiaries from living donors for kidneys, lungs, and portions of livers or intestines, and a living donor SAC must be established for each of these organs.

A TH must establish a living donor SAC before the TH bills its first living donor transplant to Medicare. The TH develops the initial living donor SAC for each living donor organ type, by estimating the reasonable and necessary organ acquisition costs it expects to incur for services furnished to living donors, and pre-admission services furnished to recipients of living donor organs during the hospital's cost reporting period. The TH divides the estimated amount by the projected number of usable living donor organs to be procured by the TH during the hospital's cost reporting period. A TH calculates its subsequent years' living donor SAC for each living organ type by using the transplant hospital's actual organ acquisition costs for the living donor organ type from the prior year's MCR, adjusted for any changes in the current year. The TH divides these costs by the actual number of usable living donor organs procured by the TH during that prior cost reporting period. Currently, when a TH/HOPO furnishes an organ to another transplant hospital or OPO, it must bill the receiving TH or OPO its SAC, by organ type, or the hospital's standard departmental charges that are reduced to cost. The TH/HOPO includes the actual incurred cost for organ procurement services in the organ acquisition cost center on the hospital's MCR.

We proposed that the costs that may be used to develop the living donor SAC

include, but are not limited to: Costs of tissue typing services, including those furnished by independent laboratories; costs of physician pre-admission transplant evaluation services; OPTN registration fees; costs for donor and recipient evaluation and workup furnished prior to admission for transplantation; other costs associated with procurement, for example, general routine and special care services related to the donor; costs of operating room and other inpatient ancillary services related to the donor; preservation and perfusion costs; and transportation costs of the excised organ. We proposed to codify these provisions at proposed new § 413.404(b)(3)(i) in new subpart L.

(b) Cadaveric Donor Standard Acquisition Charge

In the proposed rule, we proposed to codify Medicare's longstanding policy regarding TH/HOPO standard acquisition charges for cadaveric donors and the costs that may be included in the cadaveric donor SAC in new subpart L, § 413.404(b)(3)(ii) because these policies remain relevant. The cadaveric donor standard acquisition charge (cadaveric donor SAC) is an average cost that a TH/HOPO incurs to procure an organ from a cadaveric donor. The TH/HOPO calculates its initial cadaveric donor SAC for each cadaveric organ type, by estimating the reasonable and necessary costs it expects to incur in procuring cadaveric organs, combined with the expected costs of acquiring cadaveric organs from OPOs or other THs. The TH/HOPO divides this estimated amount by the projected number of usable cadaveric organs to be procured by the TH/HOPO within the TH's cost reporting period.

The TH/HOPO calculates its subsequent years' cadaveric donor SAC for each cadaveric organ type, by using the transplant hospital's actual organ acquisition costs for the cadaveric donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year. The TH/HOPO divides this estimated amount by the actual number of usable cadaveric donor organs procured by the TH/HOPO during that prior cost reporting period. ''Usable'' organs are discussed in section II.C.2.h.(2). of this final rule with comment period.

Where the TH/HOPO furnishes the organ to an OPO or another TH, the TH/HOPO uses its cadaveric donor SAC to bill the OPO or the TH receiving the organ. We also proposed that costs that may be used to develop the cadaveric donor SAC include, but are not be limited to: Costs of organs acquired from other THs or OPOs; costs of transportation of the excised organs; surgeons' fees for excising cadaveric organs (currently limited to $1,250 for kidneys); costs of tissue typing services, including those furnished by independent laboratories; preservation and perfusion costs; general routine and special care service costs; and operating room other inpatient ancillary service costs.

(3) Independent OPO Standard Acquisition Charge

In the proposed rule, we proposed that new § 413.404(c) in new subpart L would specify Medicare's longstanding policy regarding IOPO standard acquisition charges for cadaveric donors because these policies remain relevant. An OPO is required under section 371(b)(1)(C) of the PHS Act (42 U.S.C. 273(b)(1)(C)) to have an agreement with the Secretary to be reimbursed under Medicare for the procurement of kidneys. The IOPO's Medicare contractor establishes the kidney SAC, which is considered an interim rate as currently specified in § 413.200(d) (proposed to be added to new subpart L as § 413.420(d)), and which consists of an estimate of the reasonable and necessary costs the IOPO expects to incur procuring cadaveric kidneys during the IOPO's cost reporting period. The contractor divides the estimated amount by the projected number of usable [32] cadaveric kidneys procured. The IOPO's Medicare contractor may adjust the kidney SAC during the year, if necessary, for cost changes. Because the contractor must establish and may adjust, if necessary, the kidney SAC, the IOPO cannot charge or change its kidney SAC without the contractor's approval.

The Medicare contractor develops an IOPO's initial kidney SAC based on the IOPO's budget information. The kidney SAC for subsequent years is based on the IOPO's cost report, that is, costs of operating during its prior cost reporting year and the number of usable cadaveric kidneys procured during that cost reporting period. These standard charges are the basis for the interim rate (that is, the kidney SAC) paid by the TH to the IOPO. When the IOPO bills the TH for its kidney acquisition services, the TH is responsible for paying the IOPO's interim rate (that is, its kidney SAC). The IOPO's submitted cost report is used to reconcile kidney acquisition costs under § 413.200(d) (proposed to be added as § 413.420(d)).

An OPO is required under (42 U.S.C. 273(b)(1)(B)) to have accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization. As such, an IOPO establishes non-renal SACs based on its costs of procuring organs, similar to procedures followed by transplant hospitals. An IOPO develops its SACs for each type of non-renal organ, by estimating the reasonable and necessary costs it expects to incur for services furnished to procure cadaveric donor non-renal organs during the IOPO's cost reporting period. The IOPO divides this estimated amount by the projected number of cadaveric donor non-renal organs the IOPO expects to procure within its cost reporting period.

When an IOPO receives an organ from another IOPO, the receiving IOPO is responsible for paying the procuring IOPO's SAC. The IOPO uses its own SAC and not the SAC paid to another IOPO, when billing a TH receiving the organ. For example, IOPO A has a SAC of $35,000 and IOPO B has a SAC of $50,000. IOPO A receives an organ from IOPO B and pays IOPO B their SAC of $50,000. IOPO A furnishes the organ to the TH and bills the TH its SAC of $35,000.

Comment: Some commenters provided feedback regarding ''imported'' organs, or organs one OPO receives from another OPO or from a transplant hospital. A commenter noted that when an OPO receives an organ from another OPO, the receiving OPO must pay the procuring OPO's SAC, but then only charge the TH its own SAC, regardless of whether the amount is higher or lower than the procuring OPO's SAC. The commenter opined that given the revised allocation methodologies now in use, there has been a dramatic increase in the number of organs exchanged between OPOs. Other commenters noted increased costs, such as transportation, due to the new allocation methodologies. A few commenters requested that an OPO's SAC for any imported organ (renal or non-renal) incorporate the cost of the imported organ to ensure that the OPO can bill the transplant hospital an amount sufficient to fully recoup the costs incurred for procuring the imported organ from another OPO. A commenter requested that CMS clarify whether OPOs will need to administratively handle all imported organs coming into the servicing OPO's area. By ''administratively handle,'' it seems the commenter refers to the OPO's arrangement for the acquisition, preservation and transportation of donated organs, and procedures to obtain payment for organs provided to transplant hospitals.

[32] See discussion of usable organs in section II.C.2.h.(2). of this final rule with comment period.

Response: The costs of ''imported'' organs are recorded as organ acquisition costs, in accordance with the finalized rule at § 413.402(b)(9), since these are the costs of organs acquired from other hospitals or OPOs. If these costs are incorporated into the OPOs' SACs, the OPO should be able to recoup its costs for imported organs transplanted into Medicare beneficiaries. The MAC calculates the IOPO's kidney SAC based on its actual costs from the prior year. However, the IOPO can ask the MAC to adjust its kidney SAC during the year if it can support a change in the cost basis, such as might occur if the OPO has an increased amount of imported organ costs.

Likewise, because the IOPO develops its own SACs for non-renal organs by estimating its expected costs for the coming year, it can include the estimated cost of non-renal organs received from another OPO or TH in its expected acquisition costs when developing its non-renal SACs. We are clarifying that similar to our policy for IOPO kidney SACs, if an IOPO experiences cost changes, the IOPO is permitted to adjust the non-renal SAC amount during the year if it can support a change in the cost basis. Therefore, we are modifying the proposed regulation at § 413.404(c)(1) to add paragraph (iii) to state that an IOPO may adjust its non-renal SACs during the year if necessary to account for cost changes.

Finally, we are clarifying that our proposals did not make pronouncements as to whether an OPO is required to administratively process all imported organs coming into its servicing area. OPOs are required to administratively process organs pursuant to the allocation methodologies set forth by HRSA.

Comment: A commenter noted that there is no comparable reconciliation for non-renal organs procured by OPOs as there is for kidneys. The commenter stated that the only way a divergence of SAC-based revenue and actual costs is recognized is through the following year's estimated SAC, and was concerned that continuation of this policy may result in fewer non-renal organs being made available for transplant. The commenter suggested CMS consider the policy further before codifying in the Code of Federal Regulations.

Response: We appreciate this comment, and agree that there is not currently a reconciliation for non-renal organs procured by OPOs as occurs with kidneys. Requiring reconciliation of non-renal organs could ensure that Medicare reasonable cost principles are followed, and may support non-renal organ transplantation. We did not propose to reconcile non-renal organs procured by OPOs; however, we will review this further and consider addressing in future rulemaking.

Comment: A commenter stated that several OPOs charge a SAC fee with add-ons to their non-renal SAC amounts, such as additional surgeon fees, transportation, or other extra costs. The same commenter opined that some non-renal SACs are over-inflated and questioned if the MACs could approve and publish the non-renal SACs. This commenter noted that with limited regulations, these issues could only be referred to the Office of Inspector General (OIG).

A different commenter provided an example where a transplant hospital may only receive $20,000 from the OPO for services to maintain the cadaveric donor when an OPO harvests two lungs, two kidneys and a heart; however, the OPO charges the hospital $70,000 for one kidney. Two commenters noted that transplant hospitals are sometimes paid by OPOs an amount far less than what their SAC payment at cost would warrant. A commenter opined that under current policy, the OPO underpayment does not negatively impact transplant hospitals because transplant hospitals must offset 100 percent of the revenue received from OPOs from allowable organ acquisition costs on the Medicare cost report. This commenter added that a transplant hospital could forego all payments from the OPO and would remain whole through its Medicare cost report filing.

Response: Our final regulation at § 413.404(a)(3) would require that an IOPO that furnishes an organ to a TH bill the TH its IOPO SAC. Billing amounts in addition to the SAC would be inappropriate as the SAC is developed by incorporating all the allowable costs of procuring an organ, and is an average charge rather than the actual cost of a particular procurement. As such, there should be no billing of the SAC plus additional amounts, nor any need to do so. As noted in a previous comment response in this section, if an IOPO experiences increased costs that the current SAC is not covering, the IOPO can ask its MAC to adjust its kidney SAC as specified in proposed § 413.404(c)(2)(iv), or the IOPO can adjust its non-renal SAC amounts if needed due to cost changes.

Additionally, an OPO is required under 42 U.S.C. 273(b)(1)(B) to have accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization. These fiscal procedures could include carefully estimating costs for the upcoming year when developing its non-renal SAC, so that the non-renal SAC is an average charge sufficient to cover procurement costs of non-renal organs. The SAC should be a reasonable estimate of average costs rather than an inflated estimate of average costs.

We believe codifying organ acquisition payment policies as we are doing in the regulation text is a step towards making our policies clearer to all stakeholders and to increasing compliance. If a MAC identifies systemic issues such as inappropriate or abusive fiscal procedures by OPOs, it can and should refer those OPOs to the OIG. We appreciate this comment about inflated SAC amounts and oversight of non-renal SACs, and are considering options for future rulemaking to strengthen policies where needed to ensure that organ acquisition costs are paid on a reasonable cost basis, and that inappropriate fiscal procedures do not impede organ procurement or transplantation.

The commenter's example appears to be a situation where a transplant hospital provided services to a cadaveric donor, but did not procure the organs; in the example, the OPO arranged for the procurement. As such, it would not be appropriate for the TH to bill the OPO its SAC, as the TH is not procuring the organ. This is discussed further in section II.C.2.l. of this final rule with comment period pertaining to donor community hospitals and transplant hospitals that incur costs for providing services to a cadaveric donor, as authorized by the OPO so that an OPO can arrange for organ procurement. In the situation where a transplant hospital actually procures the organs and furnishes them to an IOPO, in accordance with the policy finalized at § 413.404(a), the transplant hospital should bill its appropriate organ-specific SAC(s) to the IOPO, and the IOPO should pay the TH the billed SAC amount(s).

Finally, if a TH were to forego all payments from an OPO for the services the TH provides, it could affect the hospital's cash flow and could affect the OPO's year-end reconciliation of kidney acquisition costs. However, we agree with the comment that THs must offset their acquisition costs by the revenue received from OPOs, and that the reconciliation process should ensure that THs remain whole.

Comment: A commenter supported our efforts to standardize the way in which SACs for any organ are calculated. However, the commenter cautioned that inclusion of certain extraordinary expenses in SACs could result in inequitable allocation of costs

among providers, including Medicare, while being a possible barrier to innovation. The commenter suggested those extraordinary expenses be identified and segregated from the expenses included in the SAC. As an example, the commenter stated that perfusion technologies, (*i.e.* technologies that may be used to preserve, assess and in some cases recondition organs prior to transplantation), which are new and relatively expensive, have been costs historically borne by THs, but now are costs first borne by OPOs and passed to the TH as a charge in addition to the SAC. The commenter stated that requiring OPOs to include these charges in their SAC may not be financially feasible for the OPO, and may force the OPO to eliminate its offering of these new technologies. Similarly, the commenter stated that revised allocation methods result in organs traveling greater distances to recipients, requiring OPOs to incur higher transportation expenses. If these costs are included in the SAC, the commenter believes that communities with higher rates of donation will bear an inequitable share of significant transportation costs that should instead be charged directly to the transplant hospitals incurring the cost. The commenter believed that if OPOs are required to include all costs in the SAC, regardless of the amount or frequency of the expense, doing so could result in an inequitable yet material shift of expenses among providers and suggested CMS act to avoid that outcome.

Response: We appreciate the commenter's support for our SAC proposals. However, we do not believe that an IOPO's inclusion of allowable procurement costs in its organ acquisition costs creates inequities, including costs for expensive items such as innovations or increased procurement-related travel. Costs that an IOPO incurs to procure an organ should be recorded by the IOPO, which would allow them to be included in the IOPO's organ-specific SAC amounts, pursuant to §§ 413.402 and 413.404. The SAC calculation spreads the IOPO's total costs of procuring an organ over all the organs procured, as described in the proposed regulation at § 413.404(c). Organ acquisition costs are passed on to the TH when the IOPO procures an organ for the TH and bills the TH its organ-specific IOPO SAC. Our payment system for organ procurement is designed to cover the costs of organ acquisition on a reasonable cost basis, and we believe it incentivizes innovation. Therefore, we are not adopting this commenter's suggestion about excluding certain extraordinary expenses from the SAC calculation. Finally, we note that the finalized regulation at § 413.404(a)(3) requires the IOPO to bill the TH its SAC, not its SAC plus additional charges.

In summary, we are finalizing our proposals as proposed in § 413.404 of subpart L, except for the following modifications and clarifications:

- In section II.C.2.b.(1). of this final rule, we modified the proposed registry fees and the proposed transportation costs covered as organ acquisition costs to provide expanded coverage of these costs. To conform to these final changes, we modified the SAC regulation text related to costs used to develop the living donor SAC at § 413.404(b)(3)(i)(D)*(3)* to refer to registry fees specified at § 413.402(b)(6), and at § 413.404(b)(3)(i)(D)*(8)* to refer to transportation costs of the excised organ as specified at § 413.402(b)(8)(i). Similarly, we modified the SAC regulation text related to costs used to develop the cadaveric donor SAC at § 413.404(b)(3)(ii)(C)*(2)* to refer to transportation costs as specified at § 413.402(b)(8).
- In § 413.404(b)(3)(i)(D)(*7*) and § 413.404(b)(3)(ii)(C)(*5*), to add the word 'organ' to conform to the final regulation text at § 413.404(b)(5).
- In § 413.404(c)(1) to add paragraph (iii) to specify that an IOPO may adjust its non-renal SACs during the year if necessary to account for cost changes.
- In § 413.404(a)(2), we added 'organ acquisition' to more clearly specify the total costs.
- In § 413.404(b)(3)(i), we added 'organ acquisition' to more clearly specify the average cost; and in § 413.404(b)(3)(i)(C)(*1*)(*i*), we added 'organ acquisition' to more clearly specify the reasonable and necessary costs.
- In § 413.404(a)(3), we removed the phrase 'transplant hospital' and clarified that when a TH/HOPO or IOPO furnishes an organ to another TH/HOPO or IOPO, it bills its SAC to the TH/HOPO or IOPO receiving the organs.
- In § 413.404(b)(2), we replaced 'provides' with 'furnishes,' and corrected the acronym OPO to change it to IOPO.
- In § 413.404(b)(3)(i)(C)*(1),* we added 'donor' to more clearly specify the living SAC, and in § 413.404(b)(3)(ii)(B)(*2)(ii*) we added 'donor' to more clearly specify cadaveric organs;.
- In § 413.404(b)(3)(i)(C)*(2),* we added 'years' to more clearly specify the subsequent living donor SAC, and in § 413.404(b)(3)(ii)(B)*(2)* we added 'years' to more clearly specify the subsequent cadaveric donor SAC; in § 413.404(b)(3)(i)(D)(*5*), to clarify what special care services are we added a parenthetical phrase that gives intensive care unit or critical care unit services as examples of special care services.
- Corrected grammatical errors in the regulation text, to ensure that parallel structure exists, that singular pronouns describe singular nouns, and that subjects and verbs agree.

d. Accounting for Outpatient Costs and Laboratory Services

In our proposed rule in section X.B.2.d. of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25662), we explained that outpatient costs including pre-transplant evaluation service costs were described for kidneys in ILs, as well as in the Medicare Claims Processing Manual and in a CMS Change Request.[33] After non-renal organs were covered for transplantation through a CMS Ruling (for heart transplants) and through NCDs (other non-renal organs),[34] payment policies were subsequently implemented through notice-and-comment rulemaking.[35]

(1) Outpatient Costs

Section 3102.A. of the PRM describes how to account for certain hospital outpatient costs applicable to a potential organ transplant. The TH's organ acquisition costs include donor and recipient work-ups furnished prior to admission and costs of services rendered by interns and residents not in an approved teaching program. These costs would typically be billed to Medicare Part B. However, these costs are predominantly cadaveric donor related, incurred without an identifiable beneficiary, and are included in the TH's organ acquisition cost center.

[33] Part A Intermediary Letter, July 01, 1973 No. 73–25 and Part B Intermediary Letter, No. 73–22; July 1973; Medicare Claims Processing Manual (IOM 100–04, chapter 3, section 90.1.1.A. (available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*); and change request 6978, available at (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2008CP.pdf*).

[34] See CMS Ruling 87–1, April 1987; National Coverage Determinations Manual, IOM 100–03, chapter 1, Part 4, section 260 (available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf*).

[35] 52 FR 33034, September 1, 1987 (heart); 55 FR 8545, March 8, 1990 and 56 FR 15013, April 12, 1991 (liver); 60 FR 6537, February 2, 1995 (lung); 64 FR 41497, July 30, 1999 (pancreas); 66 FR 39828, August 1, 2001 (intestine, with reasonable cost coverage of acquisition costs beginning October 1, 2001).

(2) Pre-transplant Evaluation and Laboratory Services

Section 3102.C. of the PRM specifies that pre-transplant evaluation services for recipients and donors provided by the TH, including laboratory services, are paid through the organ acquisition costs of the TH. When pre-transplant laboratory tests are performed by the TH, the TH accumulates these costs in its organ acquisition cost center. The TH also includes the reasonable charges paid for physician tissue typing services provided to living donors and recipients.

(3) Histocompatibility Laboratory Services

Histocompatibility laboratories are required by the statute at section 1881(b)(2)(A) of the Act to be paid on a reasonable cost basis, in accordance with section 1861(v) of the Act. Section 413.200 sets forth the payment policy for services furnished by histocompatibility laboratories in connection with kidney acquisition and transplantation. When the laboratory services are performed by a histocompatibility laboratory, the Medicare contractor establishes interim rates which are used by the laboratory in billing a TH. The contractor disseminates information on the interim rates to all THs, OPOs, and other contractors, or posts the information on its website. The TH pays the laboratory the approved interim rate. When the laboratory bills an OPO for services, the OPO is responsible for paying the interim rate. The contractor determines the final payment to the histocompatibility laboratory for kidney-related transplant tests by reconciling interim payments and reasonable costs during final settlement of the MCR. We note that in section X.B.2.m.(6). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to move revised text from § 413.200(b) to § 413.400, and § 413.200(a), and (c) through (g), to § 413.420.

Comment: A commenter stated that our proposed rule gave no consideration to the 50 separately certified freestanding Histocompatibility Laboratories (HLA). The commenter stated that these labs provide services to OPOs and Medicare-certified transplant centers for patients in all phases of the transplant process and the Coordination of Benefits process. The commenter stated there has been no discussion of how Medicare utilization is determined for final reimbursement nor has there been an analysis of the effect of the proposed regulatory change on the payments to the free-standing histocompatibility laboratories, and urged CMS to convene a working group about this.

Response: We appreciate the work of HLAs, and believe that our final policies for OPOs should not impact HLAs because OPOs and TH/HOPOs will continue to pay HLAs an interim rate that is established by the Medicare contractor for providing pre-transplant services. We did not make any proposals related to HLA operations or payment and appreciate the commenter's recommendation to convene a working group. However, we will monitor the effects of this final rule with comment period for any unintended consequences and consider changes impacting HLAs in future rulemaking.

We are finalizing the policies as set forth in section X.B.2.d. of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule without any changes.

e. Accounting for the Cost of Services Provided to Living Kidney Donors

Section 1881(d) of the Act sets forth Medicare coverage for living kidney donors. Under section 1881(d) of the Act, any individual who donates a kidney for transplant surgery shall be entitled to benefits under parts A and B of Medicare with respect to such donation. The Act requires that reimbursement for the reasonable expenses incurred by such an individual with respect to a kidney donation shall be made (without regard to the deductible, premium, and coinsurance provisions), in such manner as may be prescribed by the Secretary in regulations,[36] for all reasonable preparatory, operation, and post-operation recovery expenses associated with such donation. It further provides that payments for post-operation recovery expenses shall be limited to the actual period of recovery. Medicare's coverage is limited to those donor expenses that are incurred directly in connection with the kidney donation.

(1) Hospital Services to a Living Kidney Donor

When a living donor receives hospital outpatient services (before admission for excising the donor kidney) for a medical evaluation in anticipation of a kidney donation, costs of all hospital services applicable to medical evaluation are considered kidney acquisition costs. When the living donor subsequently enters the hospital for the actual excision, the hospital costs of services rendered to the donor will continue to be treated as kidney acquisition costs under Part A.[37]

The donor of a kidney for a Medicare transplant is covered for an unlimited number of days of inpatient care in connection with the organ removal operation. Days of inpatient hospital care used by the donor in connection with the organ removal operation are not charged against either party's utilization record.

Comment: A commenter objected to our use of ''admitted'' to describe a living kidney donor who receives a medical evaluation at the hospital in anticipation of kidney donation. The commenter stated that these pre-donation evaluations occur on an outpatient basis, therefore the patient is not ''admitted.''

Response: We agree with this commenter, and have revised the language in this and in the following subsection accordingly.

(2) Physician Services to a Living Kidney Donor

When a living donor receives hospital outpatient services (before admission for excising the donor kidney) for a medical evaluation in anticipation of a kidney donation, costs of all physicians' services applicable to medical evaluation are considered kidney acquisition costs. When a living donor is admitted to a hospital for the kidney excision, physician services are no longer considered kidney acquisition costs and are not reimbursable under Part A. Under the Medicare Physician Fee Schedule, surgical excision of living donor kidneys is included in the global surgery policy, with a reasonable post-surgical follow-up defined as 90 days.[38] This standard 90-day post-operative period includes all services by the primary surgeon during this period unless the service is for a condition or issue unrelated to the diagnosis for which the surgery is performed or is for an added course of treatment other than normal recovery from the surgery. During the donor's inpatient stay for the excision surgery and during any subsequent donor inpatient stays resulting from a direct complication of the organ donation, physician services are billed under Part B. They are billed in the normal manner but under the recipient's MBI at 100 percent of the fee

[36] 42 CFR 409.18, 42 CFR 409.89 (Part A); 42 CFR 410.55, 42 CFR 410.163 (Part B).

[37] 42 CFR 409.18.

[38] See Addendum B in 59 FR 63515, for CPT code 50320, which is for living donor kidney excision.

schedule,[39] with no deductible or coinsurance.[40]

(3) Living Kidney Donor Follow-Up

Costs incurred by the TH for routine kidney donor follow-up care are included in the TH's organ acquisition cost center. For routine follow-up care, the period of postoperative recovery ceases when the donor no longer exhibits symptoms related to the kidney donation. Beyond the 90-day global payment period, routine follow-up services are billed to Part B using the recipient's MBI. Routine follow-up services billed to Medicare by a physician other than the operating physician for up to 3 months following donation surgery must be billed using the recipient's MBI. The Medicare Administrative Contractor will review claims for services rendered more than 3 months after kidney donation surgery. Medicare may cover routine follow-up examinations up to 6 months after the kidney donation to monitor for possible complications. In all of these situations, the kidney donor is not responsible for co-insurance or deductible amounts.[41]

The OPTN collects follow-up data at 6 months, 12 months, and 24 months post-donation.[42] Routine clinical visits to comply with the OPTN follow-up data collection are not allowable nor reportable as organ acquisition costs on the MCR and cannot be billed to Medicare. These follow-up visits are intended as a precautionary measure to provide proactive assessment of the organ function of a living donor in the near-term following removal of an organ intended for transplant. However, medical services for a living kidney donor who experiences a complication directly related to the kidney donation procedure can be billed under the Medicare transplant recipient's MBI. Also, as described in section II.C.2.e.(4) of this final rule with comment period, hospital services for a living non-renal organ donor who experiences complications directly related to the non-renal organ donation must be reported on the Medicare cost report as organ acquisition costs.

Comment: Several commenters interpreted our proposal as eliminating payments for living donor follow-up. A commenter requested that CMS clarify that the 90-day reference is for physician services and that there is no specified time limit for hospital services to be considered allowable organ acquisition for routine living donor follow-up. Several commenters disagreed with our assertion that the living donor follow-up visits required by the OPTN were not for meeting the medical needs of the donor, and requested that CMS allow these costs.

Response: We greatly appreciate living donors and their altruistic decision on behalf of another person. Given the confusion on our policy that was made clear in comments, we wish to clarify that payments for living donor follow-up are not being eliminated, and reiterate that we did not propose any changes to our existing policies related to living donor follow-up visits. We are also clarifying that our reference to the 90-day global payment period is referring to the surgeon's follow-up period after surgery; Medicare may cover routine follow-up examinations up to 6 months after the kidney donation to monitor for possible complications. Finally, we continue to believe that the OPTN-required living donor follow-up data collection is not primarily focused on the medical needs of individual living donors and that this data collection is primarily for collecting longer term data on the effects of living donation. While we appreciate that this data collection may benefit future living donors, we are continuing our existing policy that Medicare does not cover or pay for this OPTN-required data collection.

(4) Provisions Related to Living Donor Complications

In section X.B.2.e.(4). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we stated that living kidney donor complications related to the surgery to remove a kidney, which occur after the date of discharge, are not considered kidney acquisition costs. Living kidney donor complications are statutorily authorized to be paid under Part A or Part B in section 1881(d) of the Act, with no liability for deductibles or coinsurance.[43] Under 42 CFR 409.18, Medicare covers costs incurred for living kidney donor complications only if they are directly related to the kidney donation. Rather than being paid as kidney acquisition costs, costs incurred for complications arising after the kidney donor's discharge date are billed under the Medicare transplant recipient's MBI, including facility costs and physician services. The contractor reviews costs for kidney donor complications billed under the transplant recipient's MBI. We proposed to codify this longstanding policy by adding 42 CFR 413.402(c) to new subpart L.

Comment: A commenter was concerned that CMS is narrowing the definition of complications by underscoring in proposed § 413.402(c)(2) the requirement that any complications be directly attributable to a kidney donation. The commenter did not find a specific basis for such a narrow scope in section 1881(d) of the Act. The commenter stated that the language in § 413.402(c) could be confusing as proposed paragraph (c)(1) notes that certain complications post-discharge are not kidney acquisition costs, which could have a ''chilling effect.'' The commenter suggested CMS change ''directly attributable'' to ''reasonably related.''

Response: We proposed to codify the existing policy for living kidney donor complications in accordance with our statutory authority section 1881(d) of the Act. Section 1881(d) of the Act entitles an individual who donates a kidney for transplant surgery to Medicare benefits under parts A and B, for all reasonable preparatory, operation, and post-operation recovery expenses, limited to the actual period of recovery, associated with such donation. Prior to the enactment of section 1881 of the Act, Medicare covered post donation complications for living kidney donors, as outlined in the IL 74–23.

Regarding the commenter's opposition to our using the phrase ''directly attributable'' in the regulation text, we are changing the language in the final regulation at § 413.402(c)(1) to replace ''directly attributable'' with ''directly related'' to match the language used in 42 CFR 409.18(b), which specifies that Medicare pays for postoperative recovery services directly related to the kidney donation. We disagree with the commenter that there is no specific basis for such a narrow scope in section 1881(d) of the Act, as we do not believe that our original language or this revised language is a stricter policy than that permitted by the statutory language, and note that the statute explicitly permits the Secretary to define how reimbursement occurs for the reasonable expenses incurred by a

[39] 42 CFR 410.55 and 410.163.

[40] 42 CFR 410.55 and 410.163. See also the kidney policy for living donors, which is described in the Medicare Benefit Policy Manual 100–02, chapter 11, section 140.5, available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf* and billing instructions in the Medicare Claims Processing Manual 100–04, chapter 3, section 90.1.1.F. and G., available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf.*

[41] 42 CFR 410.163.

[42] Information from *https://optn.transplant.hrsa.gov/resources/guidance/procedures-to-collect-post-donation-follow-up-data-from-living-donors/*, accessed on March 16, 2021.

[43] Section 1881(d) of the Act; 42 CFR 409.18, 409.89 for Part A costs; 42 CFR 410.55 and 410.163 for Part B costs.

living donor with respect to a kidney donation in regulations.

We believe our proposed regulation text at § 413.402(c)(1) that living kidney donor complications are not considered organ acquisition costs, was unclear and was misunderstood. Living kidney donor complications are organ acquisition costs, but they are not reported on the cost report or paid through the cost report as organ acquisition costs, because of the statutory authority in section 1881(d) of the Act. Instead, the costs of living kidney donor complications are billable under Medicare Part A and B using the Medicare kidney transplant recipient's MBI as established by regulations. The costs and charges associated with the living kidney donor complications are reported on the cost report as normal patient care expenses and not organ acquisition costs or charges. Payment is made through the claims processing system. Therefore, we make a distinction about covered organ acquisition costs that are paid through the Medicare cost report as organ acquisition costs. To make this distinction clearer, we are removing language that living kidney donor complications are not considered kidney acquisition costs from the proposed regulation text at § 413.402(c)(1), and specifying that costs of living kidney donor complications must not be reported as kidney acquisition costs on the Medicare cost report.

Comment: Several commenters were concerned that CMS' proposed codification of the payment policy for living kidney donor complications only focused on kidneys and did not address living donor complications associated with non-renal organs. Commenters noted that our proposed language generally followed the language in PRM 15–1, § 3105.B, but changed the word ''organ'' to ''kidney.'' Commenters requested that CMS affirm that it will continue covering post-discharge complications related to living organ donation for all organs furnished to Medicare beneficiaries. Commenters stated that the policy given in PRM 15–1 § 3105 is not specific to kidney and that if coverage of living donor complications for non-renal organs were to cease, it could limit the availability of living donor non-renal organs.

Response: We appreciate this comment and believe that covering living donor complications for all organs, renal and non-renal, more strongly supports living organ donation. As discussed in a previous comment response, we have explicit statutory authority to cover living kidney donor complications in accordance with section 1881(d) of the Act. Living kidney donor complications are separately billable under Medicare Part A and B using the Medicare kidney transplant recipient's MBI. The payment for living kidney donor complications is made through the claims processing system, and living kidney donor complications are not reported as kidney acquisition costs on the cost report.

While we do not have a similar statutory authority to pay for living non-renal donor complications in the same manner, we do consider the hospital costs related to living non-renal donor complications to be organ acquisition costs. We recognize that there was a change to our policy manuals that resulted in this confusion on how to bill, report, or obtain payment for living non-renal donor complications.

Therefore, we are clarifying that certain costs for living non-renal donor complications are included in organ acquisition costs when the living non-renal donor complication is directly related to the living non-renal organ donation. These hospital costs for living non-renal donor complications are not separately billable to Medicare using the recipient's MBI, but must be reported and paid through the hospital's MCR as organ acquisition costs. We believe these clarifications in response to comments will expand our proposed codification to cover both living kidney donor complications and hospital costs related to living non-renal donor complications, but through different reporting and payment mechanisms.

In response to public comments, we are modifying our proposal to codify living kidney donor complications and based on comments received to clarify appropriate billing, reporting and payment under § 413.402(c)(1) to specify that living kidney donor complications directly related to the kidney donation, which occur after the date of the donor's discharge, must not be reported as kidney acquisition costs on the Medicare cost report. We are also codifying our proposals under § 413.402(c)(1)(A) to specify that Medicare covers reasonable costs incurred for living kidney donor complications only if they are directly related to a kidney donation for a covered transplant into a Medicare beneficiary and § 413.402(c)(1)(B) to specify that living kidney donor complications are paid through the claims processing system under Medicare Part A or Part B, as applicable for the services provided, with no donor liability for deductibles or coinsurance. Living kidney donor complications are billed under the MBI of the transplant recipient.

Based on comments received, we are also codifying a provision for living non-renal donor complications under § 413.402(c)(2) to specify that hospital costs incurred for living non-renal donor complications directly related to the non-renal organ donation, which occur after the date of the donor's discharge, are not paid through the claims processing system but are reported as organ acquisition costs on the hospital's Medicare cost report. In response to comments, we are also codifying under § 413.402(c)(2)(A) to specify that Medicare covers reasonable hospital costs incurred for living non-renal organ donor complications only if they are directly related to a non-renal organ donation for a covered transplant into a Medicare beneficiary and § 413.402(c)(2)(B) to specify that hospital costs incurred for living non-renal organ donor complications are reported as organ acquisition costs on the hospital's Medicare cost report, and paid through the cost report on a reasonable cost basis.

We believe that finalizing these modifications to our proposed regulation text at § 413.402(c) is responsive to commenters, clarifies the regulations, and supports living organ donation.

Comment: Commenters were also concerned that CMS did not specify an effective date and thus perceived the proposal to be effective retroactively. Commenters requested that CMS clarify that these policies are effective October 1, 2021.

Response: As discussed previously, the proposals being finalized in section II.C.2. of this final rule with comment period are effective for cost reporting periods beginning on or after the effective date of this final rule with comment period, unless otherwise specified. None of our proposals were proposed to be retroactive except for the codification of two statutory provisions, which were effective in accordance with their statutory effective dates and which are discussed in a response in section II.C.2.b.(1). of this final rule with comment period. We are finalizing our proposals in section II.C.2.e. of this final rule with comment period with modifications, effective for cost reporting periods beginning on or after the effective date of this final rule with comment period.

f. Accounting for the Cost of Services Provided to Transplant Recipients

Certain costs related to organ transplant recipients are not organ acquisition costs, but instead are billed

under Part B to the transplant recipient's MBI. These costs include standard backbench preparation services; physician services for the surgeon who performs the transplant (and sometimes performs other surgical procedures at the time of the transplant) and provides 90 days of post-operative surgical care;[44] and/or immunosuppressant therapy management; and recipient laboratory services which occur after discharge from the hospital. See the Medicare Claims Processing Manual, IOM 100–04, chapter 12, sections 30.6.3, 40.1, and 40.4 for more details on these services.[45]

We received no comments on this section.

g. Codification of Statutory Provisions Related to Pancreata Used for Pancreatic Islet Cell Transplants

Our longstanding policies related to pancreata used for pancreatic islet cell transplants were discussed in our proposed rule. Section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003[46] (MMA) requires Medicare to pay for items and services that are reasonable and necessary routine patient care costs related to acquisition on or after October 1, 2004, and delivery of pancreatic islet cells for transplantation into Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial of islet cell transplants. The pancreata procured for islet cell transplants require the same quality and care to procure as pancreata procured for solid organ transplants. Therefore, as described in section II.C.2.a.(2). of this final rule with comment period, we are defining for organ acquisition payment purposes, pancreata, procured on or after October 1, 2004, for the purpose of acquiring pancreatic islet cells for transplantation into individuals who are participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial, to be an organ. Accordingly, pancreata procured for islet cell transplants are treated as solid organs for procurement purposes, and pancreata procured for covered islet cell transplants must be assigned a full standard acquisition charge. We proposed to codify this policy by adding § 413.406 in part 413, new subpart L, in accordance with the statute. There are other clinical trials of islet cell transplants that are not funded by the National Institute of Diabetes and Digestive and Kidney Diseases, but section 733 of the MMA does not authorize Medicare coverage for those trials under title XVIII of the Act.

We received no comments on this section, and are finalizing this rule as proposed, with clarifying modifications to add the statutory effective date (for pancreata procured on or after October 1, 2004) to the regulation text at § 413.406(a). We are also adding language to § 413.406(b) to clarify that pancreata procured under paragraph (a) of § 413.406, for covered islet cell transplants, must be assigned a full standard acquisition charge and be treated as solid organs for procurement purposes.

h. Calculation of Medicare's Share of Organ Acquisition Costs, Counting of Organs

(1) General

Medicare currently calculates its share of organ acquisition costs for THs/HOPOs by multiplying the total allowable organ acquisition costs by the ratio of Medicare usable organs (the numerator) to total usable organs (the denominator) reported on the Medicare hospital cost report.[47] To ensure that a TH/HOPO's organ acquisition costs are accurately allocated to the Medicare Program, THs/HOPOs must accurately count and report Medicare usable organs and total usable organs on their MCRs.

For IOPOs, Medicare currently calculates its share of kidney acquisition costs by multiplying the total allowable kidney acquisition costs by the ratio of Medicare usable kidneys (the numerator) to total usable kidneys (the denominator) reported on the Medicare IOPO cost report.[48] Similarly, IOPOs must accurately count and report on their MCRs the number of kidneys they procure and furnish to THs or other OPOs, to ensure that kidney acquisition costs are accurately allocated to the Medicare Program.

(2) Medicare Usable Organs, Total Usable Organs, Medicare Usable Kidneys, and Total Usable Kidneys

Currently, Medicare reimburses THs/HOPOs for their reasonable costs incurred to acquire ''Medicare usable organs.'' For Medicare to calculate its share of organ acquisition costs, currently the THs/HOPOs must include the following as Medicare usable organs:[49] (1) Organs transplanted into Medicare beneficiaries; (2) organs transplanted into Medicare beneficiaries that were partially paid by a primary insurance payor in addition to Medicare; (3) organs furnished to other THs or IOPOs; (4) kidneys transplanted into Medicare Advantage (MA) beneficiaries for dates of service on or after January 1, 2021;[50] (5) kidneys furnished to United States military renal transplant centers (MRTCs) with a reciprocal sharing agreement with the HOPO in effect prior to March 3, 1988, and approved by the contractor; and (6) pancreata procured on or after October 1, 2004, for the purpose of acquiring pancreatic islet cells for transplantation into Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial in accordance with section 733 of the MMA, as discussed in section II.C.2.g. of this final rule with comment period.[51] (For counting purposes, the TH/HOPO does not count pancreata procured for islet cell transplant as a solid organ, but counts the number of Medicare beneficiaries who received these islet cell injections as the proxy for Medicare usable organs. For example, if a TH/HOPO procured pancreata for islet cell transplant and injected these islet cells into three Medicare beneficiaries and four non-Medicare patients during its cost reporting period, the TH/HOPO enters three in the Medicare usable organ count, and seven in the total usable organ count, on its Medicare hospital cost report.)

In our proposed rule, we stated that Medicare does not intend to share in the cost of acquiring organs not transplanted into Medicare beneficiaries (except those organs designated for transplant but subsequently determined to be unusable). To calculate Medicare's share, organs not transplanted into Medicare beneficiaries must be counted as total usable organs in the denominator of the fraction of Medicare usable organs to total usable organs.

[44] See Addendum B in 59 FR 63516, for CPT codes 50360 and 50365 for kidney transplantation.

[45] Available online at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf*.

[46] Section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173); 42 U.S.C. 1395l.

[47] CMS Pub. 15–2, chapter 40, section 4028.

[48] CMS Pub. 15–2, chapter 33, section 3312.

[49] In accordance with PRM § 3115.A. and CMS Pub. 15–2, chapter 40, section 4028.3.

[50] Section 17006 of the 21st Century Cures Act, (Pub. L. 114–255). Section 17006(c) of the Cures Act amended section 1852(a)(1)(B)(i) of the Act to exclude coverage for organ acquisitions for kidney transplants from the Medicare benefits an MA plan is required to cover for an MA enrollee, including as covered under section 1881(d) of the Act. Effective January 1, 2021, these costs will be covered under the original Medicare FFS program. The MA kidney transplants will be included in the numerator and denominator on the MCR to determine Medicare's share of kidney acquisition costs. (85 FR 33796, 33824, June 2, 2020).

[51] Section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173)); 42 U.S.C. 1395l.

THs/HOPOs must include the following as total usable organs: (1) Medicare usable organs; (2) organs excised with the intention to be used for research; (3) organs excised and either transplanted or furnished to other THs or OPOs; (4) organs obtained from another OPO or transplant hospital and either transplanted or furnished to other THs or OPOs; (5) organs furnished to veterans' hospitals or organs sent outside the United States under 42 CFR 413.203; (6) organs transplanted into non-Medicare beneficiaries, under § 413.203; (7) organs for which the transplant was totally or partially paid by primary insurance other than Medicare; (8) organs for which the transplant was covered by a MA plan for dates of service prior to January 1, 2021; (9) kidneys furnished to United States MRTCs with or without a contractor-approved reciprocal sharing agreement with the HOPO in effect prior to March 3, 1988; and (10) pancreata procured on or after October 1, 2004, for the purpose of acquiring pancreatic islet cells for transplantation into participants in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial in accordance with the MMA,[52] as discussed in section II.C.2.g. of this final rule with comment period.

Medicare also currently reimburses IOPOs for their reasonable costs incurred to procure ''Medicare kidneys.'' Organ acquisition costs are not paid directly by Medicare to an IOPO. The IOPO is reimbursed for its services by the TH, subject to later reconciliation by Medicare for kidneys. Medicare currently calculates its share of kidney acquisition costs by multiplying the total allowable kidney acquisition costs by the ratio of Medicare usable kidneys (the numerator) to total usable kidneys (the denominator) reported on the Medicare IOPO cost report. For Medicare to calculate its share of Medicare kidney acquisition costs, the IOPO must include the following as Medicare kidneys: (1) Kidneys furnished to THs; (2) kidneys furnished to OPOs; and (3) kidneys furnished to United States MRTCs with a reciprocal sharing agreement with the IOPO in effect prior to March 3, 1988, and approved by the contractor. Medicare kidneys do not include kidneys furnished to VA hospitals, military hospitals, or kidneys furnished to foreign countries or transplanted into non-Medicare beneficiaries, in accordance with 42 CFR 413.202.

IOPOs must also count total usable kidneys in the denominator of the fraction of Medicare usable kidneys to total usable kidneys. IOPOs must include the following in total usable kidneys: (1) Medicare usable kidneys; (2) kidneys procured with the intention to be used for research; (3) kidneys procured and furnished to other THs or OPOs; (4) kidneys procured from another OPO or transplant hospital and either transplanted or furnished to other THs or OPOs; (5) kidneys furnished to veterans' hospitals or organs sent outside the United States in accordance with 42 CFR 413.203; (6) kidneys for which the transplant was covered by a MA plan for dates of service prior to January 1, 2021; and (7) kidneys furnished to United States MRTCs with or without a contractor-approved reciprocal sharing agreement with the IOPO in effect prior to March 3, 1988. Currently, organs excised by THs/HOPOs that are furnished to other THs or IOPOs, or kidneys furnished to MRTCs under an approved reciprocal sharing agreement in effect prior to March 3, 1988, are presumed to be transplanted into Medicare beneficiaries, even if they are not. Similarly, some kidneys that an IOPO procures and furnishes to other IOPOs, THs, or MRTCs under an approved reciprocal sharing agreement in effect prior to March 3, 1988, are presumed to be transplanted into Medicare beneficiaries, even if they are not. These categories do not have a distinction to determine whether the organs are actually transplanted into Medicare beneficiaries. In this regard, Medicare organ acquisition payment policy includes the presumption that some organs are transplanted into Medicare beneficiaries, despite the category name that suggests organs and kidneys are transplanted into Medicare beneficiaries: ''Medicare usable organs'' or ''Medicare kidneys.'' As a result, through unintended consequences, Medicare currently shares in the organ acquisition costs for some organs that are not actually transplanted into Medicare beneficiaries.

When Medicare added the ESRD benefit to Medicare coverage in 1972, Medicare presumed that most kidney transplant recipients would be Medicare beneficiaries receiving the ESRD benefit, and thus Medicare would pay a larger share of kidney acquisition costs.[53] As Medicare added benefits for transplantation of non-renal organs and included the costs to procure non-renal organs, Medicare cost reporting instructions incorporated the presumption that the ultimate transplant recipient was unknown, but likely a Medicare beneficiary. Thus, when a TH furnishes an organ to another TH or to an OPO, or when an OPO furnishes an organ to another OPO or TH, Medicare assumed that some of the unknown transplant recipients are Medicare beneficiaries, and permits those organs to be counted as Medicare usable organs in the numerator of the fraction for Medicare usable organs to total usable organs, to be assured that Medicare is paying its share of organ acquisition costs.

However, Medicare declared its intention and a methodology to calculate its share of acquisition costs, for kidneys transplanted into Medicare beneficiaries only, in a 1978 **Federal Register** final rule with comment.[54] Specifically, for each kidney transplant performed on a Medicare beneficiary, the transplanting hospital shall receive a prescribed amount of reimbursement from Medicare for the pre-transplantation services of an OPA [organ procurement organization] or laboratory having such an agreement. The 1978 final rule set forth that an OPO's cost report must provide a complete accounting of the cost incurred by the agency or laboratory in providing covered services, the *total number of Medicare beneficiaries* for whom services were furnished by the agency or laboratory, and any other necessary data to enable the intermediary to determine the reasonable cost of covered services *to Medicare beneficiaries.* [Emphasis added.] Additionally, if the intermediary determines that the interim rate payments exceeded the reasonable cost of the services furnished, then the OPA or histocompatibility laboratory *must pay the excess amount per Medicare patient* to the intermediary. [Emphasis added.] These multiple declarations in the 1978 final rule establish Medicare's intention to pay for kidney acquisition costs incurred for kidneys transplanted into Medicare beneficiaries and were originally codified at 42 CFR 405.436 and later moved to 42 CFR 413.178 (currently reserved).

The longstanding policy that Medicare must only share in organ and kidney acquisition costs for Medicare beneficiaries is also set forth in 42 CFR 413.202 and 413.203. Section 413.202 requires OPOs to separate from Medicare allowable costs, acquisition costs for procuring kidneys furnished to foreign transplant centers and kidneys transplanted in non-Medicare patients. Similarly, § 413.203 requires THs to

[52] Id.

[53] Intermediary Letter 73–25 (July 1973) and 54 FR 5619, February 6, 1989.

[54] 43 FR 58370, December 14, 1978.

separate from Medicare allowable costs, acquisition costs for procuring organs furnished to foreign transplant centers and organs transplanted in non-Medicare patients. In a 1988 proposed rule, CMS expressed belief that allowing all kidneys to be counted as Medicare kidneys was not aligned with anti-cross subsidization principles set forth in section 1861(v)(1)(A) of the Act. 53 FR 6672 at 6673 (March 2, 1988). CMS stated that the Medicare Program has always paid the total costs of OPAs [OPOs] because we assumed that all kidneys procured were for Medicare beneficiaries. However, we now realize that this assumption is incorrect and that technology has allowed a significant number of kidneys to be shipped overseas. Since the Medicare Program has been paying the cost of procuring kidneys shipped overseas or transplanted into non-Medicare beneficiaries, we believe that some action needs to be taken. We believe it is necessary to amend the regulations in order to effectuate the statutory principles embodied in section 1861(v)(1)(A) of the Act. Section 1861(v)(1)(A) of the Act requires that the cost of services be borne by the appropriate payor. Accordingly, the cost associated with the kidneys not used by Medicare beneficiaries must be borne by the responsible individual or third-party payor. Medicare is precluded from paying any costs associated with kidneys not used by Medicare beneficiaries. 53 FR 6672 at 6673 (March 2, 1988).

Medicare's decades-old presumption that most kidney transplant recipients are Medicare beneficiaries was also applied to non-renal organs because of the lack of organ tracking capabilities over the years and has led Medicare to reimburse THs and OPOs for organ acquisition costs for organs that were not actually transplanted into Medicare beneficiaries. Similar to the beliefs expressed in the 1988 proposed rule, we believe that organ tracking capabilities allow transplant hospitals and OPOs to discern organ recipients' health insurance payor information so that organ acquisition costs can be more appropriately assigned to the Medicare Program for organs transplanted into Medicare beneficiaries. The Scientific Registry of Transplant Recipients (SRTR) [55] collects and maintains data from the OPTN that identifies, among other things, transplant recipients and their health insurance payors. Data obtained from SRTR show the percentage of transplants where Medicare was the recipients' payor to all transplant recipients' payors, by organ type. We compared the SRTR data for years 2017 and 2018, to the Medicare share ratio for Medicare usable organs (including kidneys) to total usable organs, for 2017 and 2018. Table 1 reflects these data. In the majority of organ types, the SRTR percentages of transplant recipients who were actual Medicare beneficiaries were lower than the Medicare share percentages for those same years. Although there is a difference in the calendar year data from SRTR and the cost reporting fiscal year data from the MCR, these data show that the majority of SRTR's percentage of Medicare transplant recipients was less than the percentages of Medicare's share compared to 2017 and 2018 submitted MCR data from the Worksheet D–4.

TABLE 1—OVERALL ORGAN-SPECIFIC RATIOS, MEDICARE SHARE FROM COST REPORT DATA VS. SRTR MEDICARE PAYOR RATIO, 2017 AND 2018 *

Organ type	2017 Medicare ratio (Medicare usable organs/total usable organs) (%)	2017 SRTR ratio of actual transplants with Medicare as payor (%)	2018 Medicare ratio (Medicare usable organs/total usable organs) (%)	2018 SRTR ratio of actual transplants with Medicare as payor (%)
Kidney	68.2	58.9	67.8	58.6
Heart	42.0	31.6	42.8	33.0
Liver	39.1	28.4	38.6	29.2
Lung	44.2	43.9	46.6	45.7
Pancreas	61.6	49.1	58.0	45.8
Intestine	18.1	14.7	14.9	15.4

* Scientific Registry of Transplant Recipients. Request for Information. Requested on 01/29/2021.

Data from the OPTN also show the percentage of organs transplanted in 2018, by organ type, that were paid by Medicare, including Medicare Fee-For-Service and Medicare Choice, and other non-Medicare payor categories. These data are reflected in Table 2.

TABLE 2—OVERALL ORGAN-SPECIFIC PAYOR RATIOS INCLUDING NON-MEDICARE PAYORS', FROM OPTN 2018 ^

Organ type (%)	Private insurance (%)	Medicaid/CHIP (%)	Medicare Choice (%)	Medicare FFS (%)	Other * (%)	Total (%)
Kidney	30.2	7.1	14.0	42.7	6.0	100.00
Liver	48.2	18.4	10.7	18.6	4.2	100.00
Pancreas	9.8	4.2	1.1	3.3	**81.6	100.00
Heart	44.7	18.2	15.0	17.9	4.1	100.00
Lung	41.5	9.3	22.4	23.3	3.5	100.00
Intestine	40.4	37.5	7.7	7.7	6.7	100.00

^ Organ Procurement and Transplantation Network. Accessed on 09/13/2021.
Note: Combination transplants (heart/lung, kidney/pancreas) are included under each affected organ type.
* Other includes transplants covered by donations, foreign governments, free care, Veteran's Administration, other government, self-pay, or unknown.

[55] Section 373 of the Public Health Service (PHS) Act requires the operation of Scientific Registry of Transplant Recipients (SRTR) to support ongoing evaluation of the scientific and clinical status of solid organ transplantation. The U.S. Congress passed the National Organ Transplant Act (NOTA; Pub. L. 98–507) in 1984.

** This percentage is due to 833 kidney/pancreas transplants that were in the OPTN database with ''unknown'' as the payor type.

We believe that the capability exists to track the location and disposition of organs, from the time organs are excised from donors until they are transplanted into recipients. Organ tracking capability may allow THs and OPOs the ability to know the identity of all organ transplant recipients and the donor from whom the recipient's transplanted organ was excised. Knowing the identity of all organ transplant recipients, and the donor from whom the recipient's transplanted organ was excised, allows THs and OPOs the ability to also know whether a transplant recipient is a Medicare beneficiary. OPTN policy provides that OPOs use organ tracking capability,[56] and some THs also optionally use organ tracking capability. Per OPTN policies, THs and OPOs report information to the OPTN on the identity of transplant recipients and donors.[57] Additionally, the OPTN data collection forms show what data elements are currently being collected.[58] The Data System for Organ Procurement and Transplantation Network,[59] (OMB form No. 0915–0157, expiration August 31, 2023), collects the recipient's and payor's information for the transplant. The identity of the recipient and the recipient's payor is required to be reported. THs, histocompatibility laboratories, and organ procurement organizations submit required information to the OPTN's organ matching system that links all 57 OPOs, 254 THs and 150 histocompatibility labs to list patients for transplant, and matches patients with available donor organs.[60]

By way of knowing the identity of the recipient, the providers can further discern whether a recipient is a Medicare beneficiary by contacting the recipient TH or OPO to discern such payor information. Therefore, we believe it is possible for THs and OPOs to report, on their respective MCRs, the number of organs and kidneys transplanted into Medicare beneficiaries, eliminating the reason for Medicare organ acquisition payment policy to presume that some organs and kidneys are transplanted into Medicare beneficiaries, when they are not.

We believe it is necessary to update Medicare organ acquisition payment policy to recognize organ tracking capabilities and the ability for OPOs and THs/HOPOs to discern the identity of the recipient into whom the excised organ is transplanted, and whether that recipient is a Medicare beneficiary. Doing so will result in Medicare more accurately paying its share of organ acquisition costs. We believe it is necessary to require that THs and OPOs report on their cost reports only organs and kidneys transplanted into Medicare beneficiaries as Medicare usable organs and Medicare kidneys, respectively. Doing so will also help safeguard the Medicare Trust Fund and ensure that Medicare appropriately pays only its share of organ acquisition costs, and that acquisition costs for organs not transplanted into Medicare beneficiaries are not borne by Medicare. The Medicare reasonable cost principles, upon which Medicare organ acquisition payment policy is based, and the prohibition of cross-subsidization articulated in section 1861(v) of the Act require the cost of services be borne by the appropriate payor.

While all OPOs, and some THs, use an organ tracking capability, we believe that THs that do not use an organ tracking capability can also ascertain the exact recipient, and thus recipient's payor, when an organ is excised in their hospital and furnished to another TH or OPO. We understand that some THs that do not use an organ tracking capability still track organs they furnish to other THs or OPOs by using manual, written methodologies. In this regard, THs can determine the organ recipient from their records and by verifying the insurance payor of the recipient with the transplant recipient's hospital. Additionally, THs can contact the OPO to which they furnished the organ, and because the OPTN directs OPOs to use an organ tracking system, the OPO can relay the recipient's information and recipient's payor to the TH. Likewise, Medicare contractors, who review MCRs submitted by THs and OPOs, can confirm Medicare usable organs and Medicare usable kidneys reported by THs and OPOs with supporting documentation from provider's records.

Medicare kidneys include, for cost reporting statistical purposes and counting, kidneys procured by an OPO and furnished to a MRTC for transplant, in accordance with certain longstanding arrangements that existed before March 3, 1988, approved by the contractor. However, due to organ tracking capability, and to achieve equitable treatment among all OPOs (for OPOs that do not have long-standing arrangements with military THs), and to also achieve appropriate Medicare expenditures for kidney acquisition costs, we no longer believe it is appropriate to allow such kidneys to be designated as Medicare kidneys under such arrangements. Because organ tracking capability permits OPOs the ability to know a donor's transplant recipient, and thus their payor's identity, it is no longer necessary for Medicare to continue to apply its longstanding policy to deem and count all kidneys an OPO excises at, or furnishes to, a MRTC as Medicare kidneys for purposes of apportioning Medicare's share of the kidney acquisition costs.

In the proposed rule we proposed to add § 413.408(a) to new subpart L to specify that THs/HOPOs must accurately count and report Medicare usable organs and total usable organs on their Medicare hospital cost reports to ensure that costs to acquire Medicare usable organs are accurately allocated to Medicare for services provided to Medicare beneficiaries. We also proposed to add § 413.408(b) to new subpart L to specify that for cost reporting periods beginning on or after October 1, 2021, for THs/HOPOs, Medicare usable organs include only organs transplanted into Medicare beneficiaries (including kidneys for MA beneficiaries with dates of service after January 1, 2021), organs for which Medicare has a secondary payer liability[61] for the organ transplant, and pancreata procured for the purpose of acquiring pancreatic islet cells acquired for transplantation into Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial.

We also proposed to add § 413.408(c) to new Subpart L to specify that for cost reporting periods beginning on or after October 1, 2021, for THs/HOPOs, total usable organs include: (1) Medicare usable organs; (2) organs excised with the intention to be used for research; (3) organs excised and either transplanted or furnished to other transplant hospitals or OPOs; (4) organs obtained from another OPO or transplant hospital and either transplanted or furnished to other transplant hospitals or OPOs; (5) organs furnished to veterans' hospitals

[56] OPTN Policy 16, *https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf.*

[57] OPTN Policy 18, *https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf.*

[58] *https://unos.org/data/data-collection/.*

[59] *https://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0915-0157#.*

[60] *https://optn.transplant.hrsa.gov/members/.*

[61] Medicare secondary payer is governed by section 1862(b)(2) of the Act and 42 CFR 411.20 through 411.39.

or organs sent outside the United States; (6) organs transplanted into non-Medicare beneficiaries; (7) organs for which the transplant was totally or partially paid by primary insurance other than Medicare; (8) organs for which the transplant was covered by a MA plan for dates of service prior to January 1, 2021; (9) kidneys furnished to United States MRTCs with or without a contractor-approved reciprocal sharing agreement with the HOPO in effect prior to March 3, 1988; and (10) pancreata procured for the purpose of acquiring pancreatic islet cells for transplantation into participants in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial.

We also proposed to remove § 413.203, and add § 413.408(d) to new subpart L, so that all organ acquisition policies are housed together, to specify that a TH's total costs for all organs are reduced by the costs associated with procuring organs that are furnished to foreign transplant centers or transplanted in patients other than Medicare beneficiaries; and to specify that THs must separate costs for procuring organs that are furnished to foreign transplant centers and organs transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final cost settlement by the Medicare contractors. The separation of cost is achieved using the Medicare ratio set forth in proposed § 413.408(e).

We also proposed to add § 413.408(e) to new subpart L to specify that for cost reporting periods beginning on or after October 1, 2021, Medicare's share of organ acquisition costs for a TH/HOPO is calculated by multiplying the total allowable organ acquisition costs by the ratio of Medicare usable organs transplanted into Medicare beneficiaries, as specified in proposed § 413.408(b), to total usable organs, as specified in proposed § 413.408(c).

For rules pertaining to counting kidneys and calculating Medicare's share of kidney acquisition costs for IOPOs, in the proposed rule, we proposed to add § 413.410(a) to new subpart L to specify that IOPOs must accurately count and report Medicare usable kidneys and total usable kidneys on their Medicare IOPO cost reports to ensure that costs to acquire Medicare usable kidneys are accurately allocated to Medicare. We also proposed to add § 413.410(b) to new subpart L to specify that, for cost reporting periods beginning on or after October 1, 2021, for IOPOs, Medicare kidneys include only kidneys transplanted into Medicare beneficiaries.

We also proposed to add § 413.410(c) to new subpart L to specify that for cost reporting periods beginning on or after October 1, 2021, for IOPOs, total usable kidneys include: (1) Medicare usable kidneys; (2) kidneys procured with the intention to be used for research; (3) kidneys procured and furnished to other transplant hospitals or OPOs; (4) kidneys procured from another OPO or transplant hospital and either transplanted or furnished to other transplant hospitals or OPOs; (5) kidneys furnished to veterans' hospitals or organs sent outside the United States; (6) kidneys for which the transplant was covered by a MA plan for dates of service prior to January 1, 2021; and (7) kidneys furnished to United States MRTCs with or without a contractor-approved reciprocal sharing agreement with the IOPO in effect prior to March 3, 1988.

We proposed to remove § 413.202 and add § 413.410(d) to new subpart L, to specify that an IOPO's total costs for all kidneys is reduced by the costs associated with procuring kidneys furnished to foreign transplant centers or transplanted in patients other than Medicare beneficiaries; and to specify that IOPOs must separate costs for procuring kidneys furnished to foreign transplant centers and kidneys transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final settlement by the Medicare contractors. The separation of cost is achieved using the Medicare ratio set forth in proposed § 413.410(e).

We also proposed to add § 413.410(e) to new subpart L to specify that for cost reporting periods beginning on or after October 1, 2021, Medicare's share of kidney acquisition costs is calculated by multiplying the total allowable kidney acquisition costs by the ratio of Medicare usable kidneys, as specified in proposed § 413.410(b), to total kidneys, as specified in proposed § 413.410(c).

Comment: Commenters overall were not supportive of CMS' proposals for THs and OPOs to count only organs and kidneys transplanted into Medicare beneficiaries as Medicare usable organs and Medicare usable kidneys, to calculate Medicare's share of organ acquisition costs for THs and kidney acquisition costs for OPOs. Many commenters, including children's hospitals, stated they would experience a loss of revenue. Some commenters opined that this proposal would shift costs to others within the organ acquisition and transplantation ecosystem, and have the effect of raising procurement costs, although details on specifically how or which costs would increase, or how a shift in cost would occur were not provided. A commenter suggested that the policy proposal will inappropriately transfer organ acquisition costs for some Medicare beneficiaries from Medicare to the transplant hospitals that excise organs and furnish them to other THs or OPOs.

Response: We appreciate the lifesaving contributions that THs and OPOs make within the transplant community and we understand commenters' concerns over the potential loss of revenue they may experience stemming from our proposal to limit Medicare's organ acquisition costs to costs incurred for organs actually transplanted into Medicare beneficiaries. After consideration of the public comments we received, we believe these concerns warrant further review; therefore, we are not finalizing our proposed policy with respect to counting organs for determination of Medicare's share of organ acquisition costs as proposed at §§ 413.408 and 413.410, but may consider this policy in future rulemaking.

Commenters did not provide substantive information or data to explain how or why they believe costs to acquire organs would increase under our proposed policy and it is not clear to us how such costs would increase absent revenue from Medicare for organ acquisition costs for organs not transplanted into Medicare beneficiaries. We do not believe that the proposed policy would inappropriately transfer organ acquisition costs for some Medicare beneficiaries from Medicare to the transplant hospitals that excise organs and furnish them to other THs or OPOs.

When a TH excises and furnishes an organ to another TH or OPO, or when an OPO furnishes an organ to a TH or another OPO, the TH or OPO furnishing the organ currently receives revenue from the recipient TH to which the organ was furnished; the recipient TH is in turn reimbursed by the transplant recipient's payor. Even when the transplant recipient is not a Medicare beneficiary, the TH that excises and furnishes the organ to the recipient TH receives an additional payment from Medicare, because the current Medicare organ counting policy allows that organ to be counted as a Medicare usable organ and assumes that the organ is transplanted into a Medicare beneficiary. (If the organ is a kidney, the OPO receives a reconciliation payment from Medicare based on the assumption that the kidney was transplanted into a Medicare beneficiary.) If a TH incurs costs to provide services to maintain a cadaveric donor after declaration of

death and consent to donate is given, then the TH accumulates and enters those charges as organ acquisition costs on the TH's cost report, charges the OPO for the services rendered, and offsets the revenue received from the OPO for the organ acquisition costs associated with organs furnished to Medicare beneficiaries. In this regard, the TH receives revenue for its costs incurred in exchange for providing the services to the cadaveric donor, either from the OPO to which the organ was furnished, or as an amount included in its acquisition costs on its cost report.

If all payors within the transplant ecosystem are paying their share of organ acquisition costs for organs acquired for transplant into their insured recipients or Medicare beneficiaries, then there should not be an increase of an amount of unreimbursed acquisition costs.

We understand commenters' views that this proposal would result in organ acquisition costs that have been historically paid by Medicare to no longer be paid by Medicare if the organs were not transplanted into Medicare beneficiaries and that THs and OPOs will need to modify their organ tracking and billing processes in order to recoup any loss of revenue they may experience. We also acknowledge commenters' pointing out that children's hospitals may experience a loss of revenue because they traditionally have very low Medicare utilization. Specifically, we acknowledge that they noted that under the proposal, children's hospitals would experience a loss of revenue because they will only be able to count organs actually transplanted into Medicare beneficiaries, which occurs rarely with pediatric organs transplanted into adults.

In response to this proposal to count only organs transplanted into Medicare beneficiaries as Medicare usable organs, we have heard stakeholders' concerns that the process of tracking organs, to report only organs transplanted into Medicare beneficiaries on the Medicare cost report, is perceived to be burdensome. We have also heard stakeholders' concerns regarding the financial impacts from the loss of revenue from Medicare stemming from this policy proposal and the value of studying impacts to patients. We are not finalizing this proposal at this time to allow more time to better understand these and other concerns that commenters have raised, including those related to organ tracking processes, as we continue our efforts to ensure Medicare more accurately pays its share of organ acquisition costs as well as adhere to the statutory prohibition of cross-subsidization articulated in section 1861(v) of the Act.

Comment: Many commenters suggested either a withdrawal of the proposal or a delayed implementation date to allow THs additional time to re-negotiate contracts with other payors to make up for the decreased revenue they may experience stemming from the proposal. Some commenters requested that CMS delay implementation to conduct a study on the financial impact upon the transplant community as a result of the proposal. Some commenters believed that Medicare's impact estimate was underestimated and imprecise when using SRTR data reflecting organs transplanted into Medicare beneficiaries; in this regard, commenters believed the SRTR data to be underreported with recipients' payor information from transplanting THs. A commenter suggested that CMS calculate and use an ''in-house'' Medicare ratio for THs, as a proxy to apply to the number of organs the TH/HOPO furnishes to other hospitals or OPOs which are transplanted into Medicare beneficiaries. Other commenters requested that Medicare study and publish a hospital specific impact analysis resulting from these proposals.

Response: We thank commenters for sharing their concerns and requests for a delayed implementation of the proposed policy so that stakeholders may renegotiate their contracts with other payors, or conduct further analyses of their financial impacts. We agree that additional time may be needed for stakeholders to renegotiate their contracts and update their tracking and billing processes; therefore, we are not finalizing our policies proposed at §§ 413.408 and 413.410 at this time in order to further consider the public comments and financial impacts as a consequence of those proposed policies.

In response to comments about the impact analysis included in the proposed rule, we note that our impact estimate in the proposed rule was projected as a savings to the Medicare Program and was based on data collected by the OPTN and reported by the SRTR that categorizes transplant recipients by payor. THs and OPOs are required to submit information to the OPTN that are used to match donors and recipients, including the recipient's primary payor information at the time of the recipient's registration. The OPTN requires the organ recipient's payor information be updated by the transplanting hospital at the time of transplant. The SRTR derives its data from the OPTN database and we believe that these data were the best available data and a reasonable proxy for Medicare's share of organ acquisition costs for organs a TH excises and furnishes to other THs or OPOs. (See the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25665.) We also acknowledge commenters' suggestions that we could estimate the percent of organs a TH furnishes to other THs or OPOs that are transplanted into Medicare beneficiaries, by using a TH's data to calculate an in-house ratio of organs transplanted into Medicare beneficiaries within the TH's own hospital, and by applying that in-house Medicare ratio, as a proxy, to the organs a transplant hospital furnishes to other THs or OPOs.

In response to commenters' requests that CMS conduct additional analyses, we will conduct additional analyses of impacts upon THs, children's hospitals, and OPOs before we consider revising this policy in future rulemaking on counting organs as proposed at §§ 413.408 and 413.410.

Comment: Some commenters stated that Medicare's current organ acquisition payment policy was intentionally devised decades ago to ensure that Medicare provided an incentive to hospitals to participate in organ transplantation. A few commenters provided copies of a 1995 letter authored by CMS personnel that explained cost reporting instructions and audit adjustments for recording organs procured by hospitals and HOPOs, (and kidneys procured by OPOs), that were furnished to other hospitals and OPOs as Medicare usable organs and Medicare usable kidneys. Commenters opined that the methodologies discussed in the 1995 letter were an incentive for hospitals and OPOs to procure organs.

Response: We appreciate commenters bringing to our attention a 1995 letter authored by CMS personnel, however, we believe this letter explains the Medicare usable organ and Medicare usable kidney acquisition policies as they existed when the letter was authored. The 1995 letter explains that a TH or OPO that excises kidneys and furnishes them to other THs and OPOs do not have control over the disposition of the kidneys, and do not know whether these kidneys are actually transplanted, and if they are transplanted, whether they are transplanted into Medicare beneficiaries. We understand that commenters may perceive the policies outlined in the 1995 letter as providing a financial incentive for OPOs and THs to excise and furnish organs to other THs and OPOs. This was not the intention. Medicare has allowed THs

and OPOs to count all organs and kidneys excised and furnished to other THs and OPOs as Medicare usable organs or Medicare usable kidneys and required the offset of revenue; however, when revenue did not reflect the actual costs incurred, Medicare likely paid for more than its share. As we discussed in the preamble to the proposed rule, capability now exists to track the location and disposition of organs, from the time organs are excised from donors until they are transplanted into recipients. As such, we no longer believe the methodology outlined in the 1995 letter aligns with Medicare's anti-cross subsidization principles, as well as reasonable cost principles upon which Medicare's organ acquisition cost reimbursement policies are based. As stewards of the Medicare Trust Fund, it is important to establish and maintain policies that align with Medicare's anti-cross subsidization principles to ensure that Medicare pays for costs incurred for the care of Medicare beneficiaries. Other payors that may be responsible for organ acquisition costs for organs transplanted into their patients must likewise bear the cost of organ acquisition costs for their patients. Although we no longer believe the methodology outlined in the 1995 letter aligns with Medicare's anti-cross subsidization principles, or reasonable cost principles upon which Medicare's organ acquisition cost reimbursement policies are based, we understand stakeholders' concerns regarding loss of revenue and the perceived burdens to implement this proposal warrant further consideration and thus we are not finalizing the organ counting proposal. We may revisit this proposal in future rulemaking.

Comment: Many commenters expressed appreciation for the clarification and codification of organ acquisition payment policies and CMS's goal to make more precise payments for organ acquisition costs from the Medicare Trust Fund. A commenter who supported the proposal stated that the current Medicare usable organ counting policy was adopted 35 years ago when most organ donors were trauma patients at a transplant center but stated today less than a third of donors are trauma patients. It seems the commenter was suggesting that organs are procured from trauma patients at a transplant center less frequently today and more organs are being procured from other hospitals or by OPOs and sent to THs or OPOs for transplant elsewhere.

Response: We appreciate commenters' support of our intention to clarify and codify organ acquisition payment policies and our goal to make more precise payments for organ acquisition costs from the Medicare Trust Fund. We agree that over the past 35 years, the transplant ecosystem and circumstances have changed, such that more organs today are excised at one location and transported elsewhere for transplant.

Comment: Many commenters expressed concern with THs and OPOs having to track organs and report on the Medicare cost report only organs transplanted into Medicare beneficiaries, as Medicare usable organs. Some commenters stated that their administrative costs would increase under the proposed policy. Some commenters suggested that CMS develop a centralized organ tracking system and other commenters suggested that the OPTN allow all THs and OPOs access to a centralized database with updated recipients' payor information. Some commenters stated that THs were not required to update OPTN data with recipients' payor information at the time of transplant, resulting in outdated OPTN payor data for transplant recipients and likely underreporting Medicare as a payor. Some commenters opined that a TH that excised and furnished organs to other THs or OPOs would be unable to have access to organ recipients' payor data in the OPTN database. Other commenters suggested that the OPTN require THs to update their OPTN data with their transplant recipients' payor information at the time of transplant to avoid having outdated payor information if a recipient's payor status changed at the time of transplant. Some commenters opined that a TH that excises and furnishes organs to other THs or OPOs would be unable to have access to organ recipients' payor data in the OPTN database. Some commenters stated that a recipient's insurance information is entered into the OPTN database when the recipient is first placed on a waiting list for an organ, but the recipient's insurance status may change over time and not be updated in the OPTN database, remaining the same as when the recipient was first placed on the waiting list. A commenter suggested that the Medicare contractor provide verification as to whether a Medicare usable organ recorded on the cost report was actually transplanted into a beneficiary. Another commenter suggested that the Medicare contractor routinely provide beneficiary insurance status to the OPOs, instead of the OPOs contacting the transplant center to which they furnished the organ to discern whether the organ recipient was a Medicare beneficiary.

Response: We appreciate commenters' concerns regarding the burden in implementing this policy and accordingly have decided not to issue a final rule on counting of organs as proposed at §§ 413.408 and 413.410 at this time.

Although we are not finalizing our proposals at §§ 413.408 and 413.410, we are aware that OPOs have access to the OPTN database and to the identity of the recipients of each organ procured by that OPO. We also understand that all THs know the correct up-to-date primary payor of each of their transplant recipients (and the Medicare beneficiary status) at the time of transplant as this information is necessary for the TH to accurately submit its claim for reimbursement for the procedure. We note that OPOs, donor hospitals, and THs rely on a close collaborative relationship involving information sharing to ensure that organs are successfully procured and appropriately placed with transplant recipients. Many OPO commenters acknowledged that they are in contact with recipient transplant hospitals to which the organ was furnished. We believe that during these communications, collaborations and encounters, when OPOs and THs coordinate the organ acquisition and transportation between the OPO and the TH, the OPO could reasonably determine whether the organ recipient is a Medicare beneficiary.

OPTN rules require that THs update their OPTN data with their transplant recipients' payor information at the time of hospital discharge but no later than six weeks after the recipient's transplant. Under 42 CFR 121.11(b)(2), OPOs and THs are required to submit to the OPTN, and the Scientific Registry, as appropriate, and to the Secretary information regarding transplant candidates, transplant recipients, donors of organs, transplant program costs and performance, and other information that the Secretary deems appropriate. Additionally, the OPTN Policy 18 sets forth data submission requirements regarding transplant recipients that THs must submit, with accuracy, to the OPTN following the organ transplant. The Data System for Organ Procurement and Transplantation Network,[62] (OMB 0915–0157, expiration August 31, 2023), collects information on recipients and recipients' payors for the organ transplant. The OPTN data collection system contains data entry fields to capture a recipient's primary payor information. We understand that an OPO or TH that excises and furnish organs to a recipient TH or OPO, may not have access to the OPTN data for the organ recipient in order to determine

[62] *https://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0915-0157#.*

the primary payor and realize that more work may be needed to ensure that the excising TH or OPO have access to this OPTN data in the future to discern the organ recipient's payor identity.

We do not believe it is the role of the Medicare contractors to provide verification or payor information for a TH or OPO to discern whether an organ may be considered a Medicare usable organ and recorded as such on the Medicare cost report. A framework to discern a recipient's payor status already exists within the OPTN database. We note that 42 CFR 413.20 sets forth requirements that providers maintain sufficient financial records and statistical data for proper determination of costs payable under the Medicare Program and must furnish such information to the contractor as necessary to assure proper payment from Medicare.

We acknowledge the concerns raised by commenters warrant further consideration and thus we are not finalizing the organ counting proposal and may revisit this proposal in future rulemaking.

Comment: A commenter indicated that the proposal was contrary to 42 CFR 412.113(d), which sets forth that payment for organ acquisition costs incurred by hospitals with approved transplant centers are made on a reasonable cost basis.

Response: We do not believe our proposals are contrary to § 412.113(d), which describes other payments made to hospitals under the prospective payment systems, and sets forth that payment for organ acquisition costs incurred by hospitals with approved transplant centers are made on a reasonable cost basis. Under the proposal, costs incurred by hospitals with approved transplant centers will continue to be paid by Medicare on a reasonable cost basis for the acquisition of organs transplanted into Medicare beneficiaries.

Comment: A commenter requested that CMS make a policy declaration with respect to revenue offsets under this proposal for organs that a TH/HOPO excises and furnishes to other THs or OPOs, or kidneys that an IOPO furnishes to THs or other OPOs, that would not be counted as Medicare usable organs. This commenter pointed out that there would be an underpayment of the organ acquisition costs attributable to Medicare beneficiaries if a revenue offset were required for organs that are not transplanted into Medicare beneficiaries. Under the current policy, because organs that a TH/HOPO excises and furnishes to other THs or OPOs are deemed or assumed to be Medicare usable organs, the revenue the excising TH/HOPO or OPO receives from the OPO or TH to which the organ is furnished must be offset from the excising TH/HOPO's organ acquisition costs. However, if an organ is not a Medicare usable organ, the revenue the excising TH/HOPO or IOPO receives must not be offset or deducted from the excising TH/HOPO's or the IOPO's organ acquisition costs.

Response: We agree with the commenter's concerns regarding revenue offsets that are not required for organs that are not transplanted into Medicare beneficiaries. Current Medicare hospital and IOPO cost reporting instructions require a TH that excises and furnishes, or an IOPO that furnishes, organs to other OPOs or THs, to offset or reduce its organ acquisition costs by the amount of revenue received from the TH or OPO, to which the organ was furnished when the organ is a Medicare usable organ.[63] Although we are not finalizing the organ counting policies as proposed in §§ 413.408 and 413.410, Medicare still requires these revenue offsets in the Medicare cost report. Doing so will accurately account for the organ acquisition costs attributable to Medicare.

Comment: Some commenters stated that the proposed policy presented privacy or Health Insurance Portability and Accountability Act of 1996 (HIPAA) concerns with THs and OPOs disclosing or receiving the payor status of an organ recipient.

Response: Although we are not finalizing our proposed rule at §§ 413.408 and 413.410 at this time, we do not believe there should be uncertainties regarding information sharing, privacy, or HIPAA concerns, especially considering the numerous consent forms patients sign as a matter of course for medical treatment. The HIPAA Privacy Rule permits disclosure of information, without an individual's authorization, for payment related operations. Medicare is seeking to make more accurate payments for organ acquisition costs by proposing to pay acquisition costs for organs that are actually transplanted into Medicare beneficiaries. We believe that a patient's disclosure of their payor information is consistent with Medicare's payment goals and is the minimum necessary information required to ensure accurate payment from Medicare. We believe that disclosure that an organ recipient is a Medicare beneficiary is permissible under the HIPAA Rule. Additionally, patient consent forms should allow for OPOs or THs to discern whether a recipient was a Medicare beneficiary without invoking HIPAA Privacy Rule violations because the patient has provided consent for such disclosure. Under regulations at 45 CFR 164.501 that set forth the privacy of individually identifiable health information, the definition of payment means activities undertaken by a health care provider to obtain or provide reimbursement for the provision of health care. Thus, the disclosure of the organ recipient's payor status falls within this scope of payment, such that there would be no HIPAA Privacy Rule violations for a TH or OPO to disclose a recipient's payor information to another TH or OPO. We believe that any information sharing, privacy or HIPAA regulatory concerns can be abated with amendments to existing financial consent forms, if necessary, whereby organ transplant recipients can consent to have their health insurance payor information released.

Comment: Some commenters questioned how they could determine whether Medicare has a secondary payer liability to count an organ as a Medicare usable organ. Several commenters disagreed with the proposal they perceived as requiring a TH that excises and furnishes organs to another TH or OPO to count those organs as Medicare usable organs when Medicare has a secondary payer liability.

Response: We appreciate commenters' concerns. Although we are not finalizing the organ counting proposals in proposed §§ 413.408 and 413.410 in this final rule with comment period, we wish to clarify for commenters that our proposals to codify, at § 413.414, our longstanding manual provisions with respect to organ acquisition costs and counting organs when Medicare is a secondary payer pertains only to a TH that performs the transplant. In this regard, a TH that excises and furnishes an organ to another TH or OPO does not have a possibility of a secondary payer payment from Medicare because the excising TH did not perform the transplant and receive the DRG payment. Thus, the transplanting TH, not the excising TH that furnishes organs to others, needs to compare the total cost of the transplant DRG amount and the organ acquisition costs, to the payment received from the primary payer to determine if there is a secondary payer liability from Medicare for the transplanting TH's organ acquisition costs. The Medicare secondary payer provisions with respect

[63] For Medicare hospital cost reports, see CMS Pub. 15–2, chapter 40, section 4028.3. For IOPO cost reports, see CMS Pub. 15–2, chapter 33, sections 3309 and 3311.

to how the TH would determine whether Medicare has secondary payer liability for organ acquisition costs are discussed in II.C.2.j. of this final rule with comment period.

Comment: A commenter suggested that the proposals could lead to more widespread use of organ recovery centers. Stakeholder sentiment is that the current policy has served as a disincentive to transport deceased donors from THs to organ recovery centers. This is because a TH cannot include on its Medicare cost report organs excised at an ORC from a cadaveric donor that was transported from the TH to the ORC for removal of the organs in the ORC. A commenter misconstrued the proposal as permitting THs to count as Medicare usable organs, those organs transplanted into Medicare beneficiaries that had been recovered in an OPO's organ recovery center from a cadaveric donor that had been transported from the TH to the OPO's organ recovery center. A commenter requested that CMS finalize a policy that allows THs to include as Medicare usable organs, any organs recovered in an OPO's organ recovery center from cadaveric donors that were transported from the TH to the organ recovery center.

Response: We appreciate commenters' concerns. However, an OPO's operation of an organ recovery center is outside of the scope of our proposals.

Comment: Some commenters suggested that the proposal to count only organs transplanted into Medicare beneficiaries as Medicare usable organs will increase wait times, waitlist mortality and morbidity for ESRD-eligible Medicare beneficiaries. Many commenters opined that the proposal would decrease organ supply and limit the number of organs that can be procured or procured ''in a financially sustainable'' manner.

Response: We appreciate commenters' concerns. Although we are not finalizing the organ counting proposal at this time and may further consider in future rulemaking, our proposal was intended to ensure that Medicare pays its share of organ acquisition costs for organs procured and transplanted into Medicare beneficiaries, protect the Medicare Trust Fund, and not impede organ supply or transplantation. Commenters did not provide specific details to support their assertion that these policy proposals would increase wait times, waitlist mortality and morbidity for ESRD-eligible Medicare beneficiaries and decrease organ supply. However, we interpret the comments to mean that THs and OPOs may be less likely to procure organs as a result of any decrease in revenue they may experience from the proposal to count as Medicare usable organs only organs transplanted into Medicare beneficiaries, even when organs are furnished to transplant recipients for whom financial responsibility rests with other payors. We note that OPOs have existing statutory duties, under 42 U.S.C 273, to conduct and participate in systematic efforts to acquire all useable organs from potential donors. OPOs also must meet the CfCs under 42 CFR 486.344 that require them to have written protocols for donor evaluation and management and organ placement and recovery that must meet current standards of practice and that are designed to maximize organ quality and optimize the number of donors and the number of organs recovered and transplanted per donor.

On December 2, 2020, CMS published a final rule that finalized two new outcome measures for OPOs, the organ donation rate and transplantation rate measures, with the goal of increasing the supply of organs available for transplants (85 FR 77898). We believe that these outcome measures will incentivize OPOs to recover more organs that will ultimately be available for transplantation. However, if an OPO's performance on the outcome measures does not improve sufficiently, CMS will open the designated service area (DSA) and allow other high performing OPOs to compete for the open DSA.

We also note that pursuant to the finalized SAC policy at § 413.404, THs establish SACs by organ type prior to their first transplant.[64] If the TH believes their SACs are insufficient, they have the ability to increase their SACs [65] or negotiate with other payors to avoid cost reimbursement disparities.

Comment: A few commenters opined that our proposal was ''to only reimburse kidney transplants for MA patients starting January 1, 2021'' and opined that CMS proposed retroactive policy provisions at proposed §§ 413.408(b)(1) and (c)(8) and 413.410(b) and (c)(6) without explanation. The commenters seemed to question why only kidneys, and not all organs, transplanted into MA beneficiaries were included in the calculation of Medicare's share of organ acquisition costs for THs and OPOs.

Response: Although we are not finalizing our proposed rule at §§ 413.408 and 413.410 at this time, we wish to clarify that we did not propose in a retroactive manner, to include kidneys transplanted into MA beneficiaries as Medicare usable kidneys for purposes of calculating Medicare's share of kidney acquisition costs. In the preamble to the proposed rule, we proposed to codify, (at proposed §§ 413.408(b)(1) and (c)(8) and 413.410(b) and (c)(6)), the statutory provision that requires Medicare to pay for kidney acquisition costs for MA beneficiaries on a reasonable cost basis for dates of service starting on January 1, 2021.[66]

The provisions of the 21st Century Cures Act, passed in 2016 (Pub. L. 114–255), changed Medicare's reimbursement methodology for the acquisition costs of kidneys transplanted into MA beneficiaries. In the preamble to the FY 2022 IPPS/LTCH PPS proposed rule, we explained in a footnote the genesis for this statutory provision (see 86 FR 25664). Section 17006(c) of Public Law 114–255 amended section 1852(a)(1)(B)(i) of the Act to exclude coverage for organ acquisitions for kidney transplants from the Medicare benefits an MA plan is required to cover for an MA enrollee, including as covered under section 1881(d) of the Act. As such, effective January 1, 2021, in accordance with the statutory provisions these costs are covered under the original Medicare FFS program and paid on a reasonable cost basis. (For more information, see the June 2, 2020 final rule (85 FR 33824). Kidneys procured for MA beneficiaries are included as Medicare usable kidneys, and are included in the numerator and denominator on the MCR to determine Medicare's share of kidney acquisition costs, despite our not finalizing §§ 413.408 or 413.410 at this time. Procurement costs for non-renal organs and transplants continue to follow existing reimbursement methodologies through MA for MA beneficiaries.

Comment: A commenter suggested that proposed § 413.408(d) may lead to doubling the estimated non-Medicare organ and kidney acquisition costs because the proposed regulation at § 413.408(d) proposes to reduce the costs associated with procuring organs furnished to foreign transplant centers or costs associated with transplanting organs in patients other than Medicare beneficiaries, and the Medicare ratio that is applied to total costs already removes these non-Medicare costs. The commenters suggested removing proposed § 413.408(d), as it appears to be unnecessary since the calculation of

[64] See 413.404(b)(3)(i)(C)(*1*) and 413.404(b)(3)(ii)(B)(*1*).

[65] See 413.404(b)(3)(i)(C)(*2*) and 413.404(b)(3)(ii)(B)(*2*).

[66] See 86 FR 25664, and 25702, and 25703.

Medicare allowable costs is achieved through proposed § 413.408(b), (c), and (e).

Response: We appreciate commenters' concerns and note this comment also applies to proposed § 413.410(d) pertaining to Medicare's share of kidney acquisition costs. We are not finalizing the proposed counting policy in §§ 413.408 and 413.410, we may further consider this issue as we consider additional rulemaking.

i. Provisions Related to Intent To Transplant, and Counting En Bloc, Research, and Discarded Organs

In the FY 2022 IPP/LTCH PPS proposed rule, we set forth our policy, pertaining to intent to transplant, counting en bloc organs, research organs, and discarded organs for THs and OPOs (86 FR 25667 through 25668). These policies provide for the proper calculation of Medicare's share of organ acquisition costs that are used for the appropriate allocation of organ acquisition costs on the MCR. The calculation of Medicare's share of organ acquisition costs is discussed in section II.C.2.h.(1). of this final rule with comment period. The methodology of counting organs to calculate Medicare's share of organ acquisition costs is used for the allocation of organ acquisition costs on the MCR and differs from Medicare's organ counting policy to assess OPOs' performance, which is set forth under the OPO CfCs, 42 CFR part 486, subpart G. To calculate Medicare's share of organ acquisition costs, when organ procurement is attempted, but no organ is actually retrieved (or the organ is instead discarded), proper counting of the organ must occur to ensure that overhead costs are appropriately allocated to Medicare and non-Medicare payors. However, cost allocation is not a factor when counting organs for evaluating an OPO's performance under the CfCs.

(1) Principle of Intent To Transplant

Medicare presumes that THs and OPOs intend to procure all donor organs that are medically suitable for transplant.[67] We proposed to add § 413.412(a)(1) to new subpart L, to specify, for organ acquisition payment purposes, an organ is intended for transplant when the OPO or TH designates it for transplant prior to the time the donor enters the hospital's operating room for surgical excision/recovery of the organ(s). Regardless of whether the OPO or TH procures organs for transplant, it incurred cost in attempting to procure organs.[68] We proposed to add § 413.412(a)(2) to new subpart L, to specify, OPOs and THs must identify the costs associated with the recovered and unrecovered organs and apportion those costs to the appropriate cost centers by organ type.

Comment: A commenter appreciated CMS clarifying and codifying long-standing CMS policy regarding intent to transplant, counting en bloc, research and discarded organs because it will help ensure more accurate reporting of total usable organs, Medicare usable organs, and organ statistics on the MCR.

Response: We appreciate the commenter's support for our clarifications of the policy regarding intent to transplant, counting en bloc, research and discarded organs. For additional clarity, we also note that an OPO or TH can demonstrate that it did not intend to procure a particular organ, if an instance such as one of the following occurs: The donor does not meet the criteria for eligible death as specified by the OPTN; the organ has been eliminated for eligibility because of donor information; the organ has been ruled out by laboratory data prior to the donor entering the operating room for excision of organs; the family does not provide consent to donate the organ or the donor is not a registered organ donor; or the search for a recipient for that particular organ has ended unsuccessfully prior to the donor's entrance into the operating room.

After consideration of the public comments we received, we are finalizing our proposals regarding intent to transplant under § 413.412(a).

(2) Counting and Cost Allocation of En Bloc Organs

In the proposed rule, we set forth our policy for counting en bloc organs for cost allocation purposes (86 FR 25668). We proposed to add § 413.412(b) to new subpart L, to specify our policy for counting en bloc organs for Medicare cost allocation purposes and to specify that en bloc organs can be en bloc lungs or en bloc kidneys.

We proposed to add § 413.412(b)(1) to new subpart L to specify that OPOs and THs count en bloc lungs or en bloc kidneys procured and transplanted en bloc (two organs transplanted as one unit) as one total usable organ. En bloc organs transplanted into a Medicare beneficiary count as one Medicare usable organ or one Medicare usable kidney.

We proposed to add § 413.412(b)(2) to new subpart L to specify that OPOs and THs count en bloc lungs and en bloc kidneys procured en bloc but separated and transplanted into two different recipients as two total usable organs. For each organ transplanted into a Medicare beneficiary, count each as one Medicare usable organ or one Medicare usable kidney.

Comment: A commenter suggested CMS' proposals relative to counting en bloc organs does not take into consideration added costs of procuring and transplanting multiple organs. This commenter perceived our proposal to codify our longstanding policy for counting en bloc organs procured for transplant as a change in policy. The commenter further indicated that this policy will reduce Medicare reimbursement and is inconsistent with Congressional intent to ensure Medicare payment policies expand access to transplantation-related services.

Response: We did not propose changes to Medicare's policy for counting en bloc organs for organ acquisition payment purposes. Our proposals are intended to codify our longstanding policy for counting en bloc organs procured for transplant as was previously set forth in manual provisions. In this regard, we did not propose changes that would change or affect how Medicare's share of costs is calculated to acquire en bloc organs for transplant. Our intent is to ensure that Medicare pays only its fair share of en bloc organ acquisition costs.

After consideration of the public comments we received, we are finalizing our proposals regarding counting of en bloc organs under § 413.412(b), with modification to remove the references to § 413.408(b) and § 413.410(b) because those provisions are not being finalized.

(3) Research Organs

In the proposed rule, we set forth our policy regarding counting of organs excised and used for research for Medicare cost allocation purposes (86 FR 25668). We proposed to clarify that for organ acquisition cost allocation purposes, a ''research organ'' is an organ procured and used for research regardless of whether it is transplanted as part of clinical care (with the exception of pancreata previously discussed in section II.C.2.h.(2). of this final rule with comment period). We proposed to add § 413.412(c) to new subpart L to specify that organs used for research are not counted as Medicare usable organs in Medicare's share of organ acquisition costs (except pancreata previously discussed in section II.C.2.h.(2). of this final rule with comment period). We also proposed to clarify that Medicare shares

[67] 86 FR 25668.

[68] 86 FR 25668.

in the costs of organs that are designated for transplant prior to the time the donor entered the hospital's operating room, but subsequently determined to be unusable and donated to research. The costs incurred are allocated among all remaining usable organs.

We proposed to add § 413.412(c)(1)(i) to new subpart L to specify that OPOs and THs do not count organs designated for research activities prior to the time the donor entered the hospital's operating room for surgical removal of the organs as Medicare usable organs. We proposed to add § 413.412(c)(1)(ii) to specify that OPOs and THs count organs designated for research activities prior to the time the donor entered the hospital's operating room for surgical removal of the organs, as total usable organs.

We proposed to add § 413.412(c)(2) to new subpart L to specify that OPOs and THs do not count organs designated for transplant prior to the time the donor entered the hospital's operating room for surgical removal of the organs but subsequently determined to be unusable and donated to research, as Medicare usable organs or total usable organs.

Comment: Overall, commenters disagreed with CMS' proposal relative to counting organs intended for research (excluding certain pancreata procured to acquire pancreatic islet cells for transplantation under proposed § 413.408) and suggested our proposal reflects a change in CMS' current policy. Several of these commenters requested we exclude organs designated for research from the count of total usable organs for the purpose of allocating costs.

A few commenters noted that the instructions in the IOPO MCR manual would need to be updated if our proposal was finalized because currently IOPOs are instructed to exclude organs intended for research from total organs and offset the revenue received from these organs against allowable cost. A commenter suggested that including organs intended for research in total usable organs results in a duplicative removal of costs for these organs because of the current MCR instructions. This commenter questioned whether CMS intended to include research organs in the allocation of all organ costs (hospital related organ procurement costs, organ acquisition overhead costs, and Medicare's share of total organ costs); and suggested the proposed rule would lower the costs reimbursed by Medicare, resulting in higher acquisition fees for research organs.

Several commenters requested clarification on the application of our proposed policy relative to organs intended for research. One such commenter requested examples of factual scenarios, similar to those CMS provided in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25669 through 25673) for accounting of kidney paired donation.

Response: We acknowledge commenters' concerns with our proposal for counting organs including research organs. Our proposal was intended to clarify the current policy for counting research organs to ensure that Medicare pays its fair share of organ acquisition costs and does not fund non-reimbursable activities such as research. Under 42 CFR 413.90(a), costs incurred for research purposes, over and above usual patient care, are not includable as Medicare allowable costs.

After consideration of the public comments received, we are not finalizing our proposed policy with respect to counting research organs in total usable organs, as proposed under § 413.412(c)(1) and (2), and may consider it in future rulemaking. However, we are finalizing at § 413.412(c) that the only research organs that may be included as Medicare usable organs are pancreata procured for the purpose of acquiring pancreatic islet cells for transplantation into Medicare beneficiaries who are participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial of islet cell transplantation in accordance with section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

Comment: Many commenters disagreed with the impact our proposal would have on Medicare's share of organ acquisition costs. These commenters indicated under the current policy Medicare covers certain donor-related costs such as testing, hospitalization, or operating room costs. These commenters claimed CMS's proposal would shift donor-related expenses and organ acquisition costs to research organizations and would negatively impact the affordability and availability of research organs and the advancement of clinical research. Several commenters also suggested our proposed policy stands at direct odds with the Biden Administration's commitment to advance clinical research.

Several commenters requested CMS not finalize the policy because of the financial impact and the impact on the availability of organs for research. Commenters suggested an impact analysis is needed on the potential negative effects of the proposed changes. A few commenters requested we delay the implementation of this proposal by one year, so as not to hinder medical research and to allow OPOs time to reapportion this significant shift in acquisition costs for research organs and medical research institutions to attempt to redirect financial resources to cover this additional cost.

Response: We acknowledge the commenters' concerns. Our proposals were not intended to impact the affordability and availability of organs used for research. However, we recognize that our proposals may impact the cost researchers and other institutions face for research organs, and may require them to pursue other methods of funding. In accordance with 42 CFR 413.90(b)(1), funds for research activities are provided under many Federal programs and by other tax supported agencies. Also, many foundations, voluntary health agencies, and other private organizations, as well as individuals, sponsor or contribute to the support of medical and related research.

We appreciate the commenters' concerns that our proposals relative to counting organs intended for research for cost allocation purposes may impede the continuation of research or clinical advancement. CMS supports efforts to advance clinical research and understands that providing organs for research supports researchers in discovering new treatments. We note that OPOs are required to conduct and participate in systemic efforts, including professional education, to acquire all usable organs from potential donors. (42 U.S.C. 273(b)(3)(B)). CMS's recent regulatory amendments for OPOs is aimed at increasing organ supply and transplantations.

We acknowledge the commenters' requests not to finalize the policy because of the financial impact and the impact on the availability of organs for research. We also acknowledge commenters' requests that we delay the implementation of this proposal by one-year and allow OPOs time to redirect financial resources to cover the costs associated with research organs.

After consideration of the public comments received, we are not finalizing our proposed policy at § 413.412(c)(1) and (2) with respect to THs or OPOs counting organs used for research, as Medicare usable organs or total usable organs, depending upon whether the organs were originally designated for research or designated for transplant. Additionally, as discussed in section II.C.2.h. of this final rule with comment period, we are not finalizing our proposal at § 413.408(c)(2) to require

TH/HOPOs to include organs excised with the intention to be used for research in total usable organs. We are also not finalizing our proposal at § 413.410(c)(2) to require OPOs to include organs excised with the intention to be used for research in total usable organs. We may consider these issues further as we consider future rulemaking.

In this final rule with comment period, we are finalizing our proposal under § 413.412(c) to require that organs used for research are not counted as Medicare usable organs in Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)) and kidneys used for research are not counted as Medicare usable kidneys in Medicare's share of kidney acquisition costs.

Comment: A commenter questioned whether the collection for umbilical cords (currently, not classified as human organs) for research is impacted by our proposal.

Response: Our proposal was specific to organs defined in § 413.400 of this final rule with comment period, which does not include umbilical cords. Accordingly, this comment is outside of the scope of this rule.

Comment: A commenter requested CMS clarify that organs intended for research will not count towards its denominator in the donation rate and transplantation rate measures. This commenter requested CMS explain how OPOs would know whether patients that are participating in the ''two kidney trials'' would continue to be reimbursed by Medicare.

Response: Comments on donation and transplantation rate measures relate to CfCs and are outside of the scope of this rule. Our proposals, which we are not finalizing, were related to counting organs to determine Medicare's share of organ acquisition costs and differ from counting organs for evaluating an OPO's performance under the outcome measures at § 486.318. We are unclear to which ''two kidney trials'' the commenter is referring. Currently, as required under section 733 of the MMA, Medicare pays for the cost to acquire pancreatic islet cells for transplantation into Medicare beneficiaries participating in a NIDDK clinical trial.

(4) Counting and Cost Allocation of Discarded/Unusable Organs

In the proposed rule, we set forth our policy regarding counting of discarded/unusable organs for Medicare cost allocation purposes (86 FR 25668). In the proposed rule, we proposed to add § 413.412(d) to new subpart L, to specify that an organ is not counted as a Medicare usable organ or a total usable organ if the excising surgeon determines, upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and the organ is determined to be unusable and discarded. This includes organs that are determined to be unusable and subsequently donated to research as previously described in section II.C.2.i.(3). of this final rule with comment period.

Comment: A commenter suggested that the proposed policy requires unrecovered organs be counted in the denominator of the Medicare fraction, which results in allocation of all related costs to non-Medicare payors; however, organs that are recovered but determined to be unusable or discarded are excluded from the denominator. This commenter suggested that both unrecovered organs, and unusable or discarded organs should be excluded from the denominator of the Medicare fraction and the costs should be treated as overhead costs of the Program and allocated pro rata between Medicare and other payors. Another commenter requested we count organs intended for transplant at the time of entry into the operating room and subsequently determined to be unusable and donated for research as Medicare usable organs. A commenter also questioned whether allowable costs for obtaining organs that are discarded without being used for research will be paid or if such costs can be included in our MCR or SAC calculations.

Response: We thank the commenters for their comments and appreciate their recommendations. We are clarifying our longstanding policy that organs determined to be unusable or discarded are not included in the count of Medicare usable or total usable organs. The cost of unrecovered organs, and unusable or discarded organs must be included in the appropriate organ cost center on the Medicare cost report. In addition, the costs associated with unusable or discarded organs are equitably allocated amongst the remaining usable organs and included in the SAC calculation set forth in § 413.404.

In light of the numerous comments received surrounding the treatment of research organs, we are finalizing our proposal under § 413.412(d) with modification to require that an organ is not counted as a Medicare usable organ or a total usable organ if the excising surgeon determines, upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and the organ is determined to be unusable and discarded and removing the language relative to organs that are determined to be unusable and subsequently donated to research. We may consider addressing organs subsequently donated to research in future rulemaking.

Comment: A commenter suggested that the proposed changes to the calculation of Medicare's share of organ acquisition costs discourages the procurement of marginal organs that may end up being unusable organs.

Response: We disagree with the commenter. Our longstanding policy requires THs and OPOs to exclude unusable organs or organs procured and subsequently determined unusable from the numerator and the denominator of the Medicare share calculation. Excluding these organs from the count allows the costs to be included and spread out amongst all the remaining transplantable organs and shared by all payors. We acknowledge that this policy was not clear in the treatment of organs determined unusable and subsequently donated to research; however, our proposal was to treat these organs the same way we treat unusable organs. We received numerous comments on the treatment of research organs in general, and on the counting of research organs and; therefore, decided not to finalize this portion of our proposal. As such, we are finalizing our proposal under § 413.412(d) with modification to remove the language relative to organs that are determined to be unusable and subsequently donated to research. We may consider addressing organs subsequently donated to research in future rulemaking.

Comment: A commenter noted IOPOs have always been required to report organs intended for research or transplant but discarded on the appropriate MCR worksheets for cost allocation purposes. This commenter requested we revise the IOPO cost report (CMS–216) accordingly.

Response: We acknowledge the commenter's request; however, because we are not finalizing our policy as proposed, we are not revising the Medicare cost report, (CMS–216) as the commenter suggested. We are finalizing our proposal under § 413.412(d) with modification to require that an organ is not counted as a Medicare usable organ or a total usable organ if the excising surgeon determines, upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and the organ is determined to be unusable and discarded, and removed the language relative to organs that are determined to be unusable and subsequently donated

to research. We may consider addressing organs subsequently donated to research in future rulemaking.

j. Provisions Related to Medicare as Secondary Payer—Organ Acquisition Costs and Medicare Organ Count

If a Medicare beneficiary has a primary health insurer other than Medicare and that primary health insurer has primary liability for the transplant and organ acquisition costs, the Medicare Program may share a liability for organ acquisition costs as a secondary payer in certain instances. Medicare prohibits secondary payment if the provider is either obligated to accept, or voluntarily accepts, as payment in full, a primary payment that is less than its charges. See 42 CFR 411.32(b). When a provider or supplier is obligated to accept as full payment an amount less than its charges, Medicare considers that lower amount to be the provider's charges. (For more information see the October 11, 1989, final rule (54 FR 41728)). In this final rule, we are codifying into the regulations the organ acquisition cost reimbursement policy with regard to Medicare secondary payer policy.

To determine whether the provider is contractually obligated to accept the primary insurer's payment as payment in full, and thus whether Medicare has zero liability as a secondary payer, it is necessary to review the provider or supplier's agreement with the primary insurer. If the primary insurer's agreement requires the TH to accept the primary insurer's payment as payment in full for the transplant and the associated organ acquisition costs, Medicare has zero liability as a secondary payer with no payment obligation for the transplantation costs or the organ acquisition costs, and the organ at issue is not counted as a Medicare usable organ.

When the primary insurer's agreement does not require the provider to accept the payment from the primary insurer as payment in full and the payment the provider receives from the primary insurer for the transplant and the organ acquisition costs is insufficient to cover the entire cost, Medicare may have a secondary payer liability for the organ acquisition costs. To determine whether Medicare has a secondary payer liability, it is necessary for the provider to submit a bill to its Medicare contractor and to compare the total cost of the transplant, including the transplant DRG amount and the organ acquisition costs, to the payment received from the primary payer. The provider's Medicare remittance advice may or may not show that Medicare has a liability because the remittance advice only reflects the transplant portion of the payment. Thus, the provider will need to compare the total Medicare cost (the transplant DRG and the organ acquisition costs) to the payment from the primary payer to determine whether Medicare has a liability for the organ acquisition costs. If the payment from the primary payer is greater than the cost of the transplant DRG and the organ acquisition costs, there is no Medicare liability and the organ must not be counted as a Medicare usable organ. If the payment from the primary payer is less than the transplant DRG and the organ acquisition costs, there is a Medicare secondary payer liability and the organ is counted as a Medicare usable organ. In this circumstance, the payment from the primary payer is pro-rated between the transplant DRG payment and the organ acquisition payment. If the organ is counted as Medicare usable, the organ acquisition portion of the primary payment must be included on the appropriate line as a revenue offset on the TH's MCR (currently Form CMS–2552). This is consistent with the cost reporting instructions in CMS Pub. 15–2, (PRM–2) chapter 40, section 4028.

Consider the following example as an illustration of Medicare's payment of organ acquisition costs as a secondary payer. A TH transplants a patient that has private health insurance and Medicare. The private health insurance is primary and Medicare is secondary. The private health insurance pays the TH $70,000 for the transplant and the organ acquisition costs; there is no requirement in the primary insurer's agreement with the provider for the TH to accept this payment as payment in full. If Medicare was the primary payer, the combined payment to the TH would have been $100,000 ($60,000 for the transplant and $40,000 for the organ acquisition costs). The TH compares the primary payer payment to the total amount Medicare would have paid if it had been primary (the transplant DRG and organ acquisition costs). The TH prorates the primary payer's payment of $70,000 between a portion of the transplant DRG and a portion of the organ acquisition costs. The TH determines the primary payer amount for the transplant DRG payment is $42,000 ($70,000 payment from the primary payer × [$60,000 for the transplant portion from Medicare/ $100,000 combined Medicare payment]) and for organ acquisition costs is $28,000 ($70,000 payment from the primary payer × [$40,000 for the organ acquisition portion from Medicare/ $100,000 combined Medicare payment]). The TH counts the organ as a Medicare usable organ on its MCR and offsets the primary payment amount ($28,000) as revenue received, thereby reducing Medicare's liability.

In the proposed rule, we proposed to add § 413.414(a) to new subpart L to set forth the general principle that if a Medicare beneficiary has a primary health insurer other than Medicare and that primary health insurer has primary liability for the transplant and organ acquisition costs, the Medicare Program may share a liability for organ acquisition costs as a secondary payer in certain instances. To determine whether Medicare has liability as a secondary payer for organ acquisition costs, it is necessary to review the TH's agreement with the primary insurer. In the proposed rule, we also proposed to add § 413.414(b) to new subpart L to set forth the circumstances when Medicare has no secondary payer liability for organ acquisition costs. If the primary insurer's agreement requires the TH to accept the primary insurer's payment as payment in full for the transplant and the associated organ acquisition costs, Medicare has zero liability as a secondary payer with no payment obligation for the transplantation costs or the organ acquisition costs, and the organ at issue is not a Medicare usable organ. We also proposed to add § 413.414(c) to new subpart L to set forth the policy for when Medicare may have a secondary payer liability for organ acquisition costs, which is based upon the provider's agreement with the primary insurer that does not require the provider to accept the payment from the primary insurer as payment in full, and the payment from the primary payer for the transplant and the organ acquisition costs is less than the provider's costs for the transplant and the organ acquisition costs. When the primary insurer's agreement does not require the TH that performs the transplant to accept the payment from the primary insurer as payment in full and the payment the TH receives from the primary insurer for the transplant and organ acquisition costs is insufficient to cover the entire cost, Medicare may have a secondary payer liability for the organ acquisition costs. To determine whether Medicare has a secondary payer liability for the organ acquisition costs, it is necessary for the TH that performs the transplant to submit a bill to its Medicare contractor and to compare the total cost of the transplant, including the transplant DRG amount and the organ acquisition costs, to the payment received from the

primary payer. If the payment from the primary payer is greater than the cost of the transplant DRG and the organ acquisition costs, there is no Medicare liability and the organ cannot be counted as a Medicare usable organ. If the payment from the primary payer is less than the transplant DRG and the organ acquisition costs, there is a Medicare secondary payer liability and the organ is counted as a Medicare usable organ. In this circumstance, the payment from the primary payer is pro-rated between the transplant DRG payment and the organ acquisition payment and the portion of the payment applicable to organ acquisition will be used on the cost report to reduce the Medicare organ acquisition costs.

Comment: A commenter suggested that when Medicare is required to pay for medical services furnished in connection with a kidney donation for a Medicare beneficiary with ESRD, the kidney should also be counted as a Medicare usable organ, regardless of whether the provider is ''either obligated to accept, or voluntarily accepts, as payment in full, a primary payment that is less than its charges.'' This commenter suggested that the proposal to codify the Medicare secondary payer provisions with respect to organ transplants is inconsistent with the statute or Congressional intent. This commenter stated that many commercial payers make no separate payment, nor identify a prorated amount, for organ acquisition costs outside of a DRG, and suggested that when Medicare pro-rates the primary payer's reimbursement between the transplant DRG and the organ acquisition payment, Medicare reduces its responsibility for organ acquisition cost. The commenter disagreed with this approach and believes it is arbitrary and capricious to allow third-party payers to dictate the level of liability Medicare has for organ acquisition costs.

Response: We appreciate the commenter's perspective; however, we note that the Medicare secondary payer policy is well established in statute at section 1862(b) of the Act and in the regulations at § 411.32, and applies to many aspects of Medicare reimbursement outside of transplant and organ acquisition cost reimbursement. We note that Medicare secondary payer policy is independent of commercial payers' approach to organ acquisition costs. As discussed in the proposed rule, § 411.32 sets forth the basis for Medicare secondary payments, and establishes that Medicare prohibits secondary payment if the provider is either obligated to accept, or voluntarily accepts, as payment in full, a primary payment that is less than its charges. In the proposed rule, we proposed to codify Medicare's longstanding policy with respect to Medicare secondary payer and organ acquisition costs so that THs that perform transplants can discern whether Medicare has a secondary payer liability for organ acquisition costs incurred by the transplanting hospital.

In section II.C.2.h.(2). of this final rule with comment period, we also addressed comments received pertaining to counting organs as Medicare usable organs when Medicare has secondary payer liability, in which we explained that only the transplant hospital that performs the transplant counts as a Medicare usable organ, an organ transplanted for which Medicare has a secondary payer liability for the organ transplant.

After consideration of the public comments we received, we are codifying the provisions related to Medicare as secondary payer for organ acquisition costs and counting Medicare usable organs as proposed at § 413.414 in new subpart L, with modifications at § 413.414(c)(3)(ii) to clarify that only the TH that performs the transplant counts the organ as a Medicare usable organ when there is a Medicare secondary payer liability.

k. Proposed Organ Acquisition Charges for Kidney Paired Exchanges

In a directed living kidney donation, the donor names a specific recipient who will receive the donor's kidney.[69] Because the donor and recipient are known prior to the organ excision and transplantation, the organ acquisition costs can be appropriately and accurately matched to the recipient's account. In a non-directed donation, the donor does not name a specific recipient for the kidney and instead, the donor is matched with a recipient in need.[70] Kidney paired exchanges are similar to directed living donations; however, when the living donor and recipient do not match, they can consent to participate in a kidney paired exchange program. Kidney paired exchanges can occur when two or more living donor/recipient pairs match each other and the donated kidneys from two or more donors are exchanged so each recipient receives a compatible kidney for transplantation.

In a kidney paired exchange, the living donor and matched recipient may have their procedures performed at different THs. When a recipient and donor elect to participate in a kidney paired exchange, the costs of the initial living donor evaluations are incurred by the originally intended recipient's TH, regardless of whether the living donor actually donates to their originally intended recipient, a kidney paired exchange recipient, or does not donate at all. The Medicare organ acquisition payment policy for kidney paired donations is currently set forth at PRM section 3106. In the proposed rule, we proposed to codify Medicare's organ acquisition payment policy with respect to KPD transactions to ensure that the kidney acquisition costs in a kidney paired exchange are documented so that the kidney acquisition costs are appropriately and accurately assigned to the transplant recipient's account, and appropriate organ acquisition payment outcomes are achieved, consistent with a directed donation.

The costs of all hospital and physician services for pre-transplant living donor and recipient evaluations become acquisition costs and are included in the MCR of the recipient's TH, regardless of whether the recipient is a Medicare beneficiary. Additionally, all total usable kidneys and all Medicare usable kidneys are recorded by the transplant hospital on its MCR so that Medicare's share of kidney acquisition costs can be computed; this is true regardless of whether the transplant results from a KPD or from a directed donation. In a kidney paired exchange, once the donor and recipient are matched, any additional tests requested by the recipient's TH, and performed by the donor's TH, are billed to the recipient's TH as charges reduced to cost (using the donor's TH's cost to charge ratio) and included as acquisition costs on the recipient TH's MCR, regardless of whether an actual donation occurs, and regardless of whether the recipient is a Medicare beneficiary. When a donor's TH procures and furnishes a kidney to a recipient's TH, the donor's TH bills the recipient's TH the donor TH's kidney SAC, or alternatively, its standard departmental charges reduced to cost, for the reasonable costs associated with procuring, packaging and transporting the kidney. The donor's TH records these costs on its MCR as kidney acquisition costs and offsets any payments received from the recipient's TH against its kidney acquisition costs. The recipient's TH records as part of its kidney acquisition costs, the amounts billed by the donor's TH for the reasonable costs associated with procuring, packaging, and transporting the organ, as well as any additional

[69] *https://www.kidney.org/transplantation/livingdonors/general-information-living-donation.*

[70] Id.

testing performed and billed by the donor's TH.

In the scenario where a donor's TH does not procure a kidney, and instead the donor travels to the recipient's TH and the recipient's TH procures the organ from the donor, the reasonable costs associated with the organ procurement are included on the MCR of the recipient's TH. As discussed in section II.C.2.b.(3). of this final rule with comment period, transportation and travel expenses of the living donor are not allowable Medicare costs. Programs outside of Medicare, such as that of the National Living Donor Assistance Center,[71]may pay for transportation costs for living donors.

Example. The following is an example of the accounting of organ acquisition costs in a kidney paired exchange for Medicare cost reporting purposes.

(Step 1), the Participants. There are 4 THs: TH A, TH B, TH C, and TH D. Each TH has a potential transplant recipient in need of a kidney and each recipient has a willing, but poorly matched, donor; thus, all donors and recipients enter into a kidney paired exchange. Each recipient and donor pair have been evaluated at their respective TH.

- *TH A.* Recipient A is a patient of TH A. TH A evaluates three potential living donors for Recipient A before a donor, Donor A, is identified. The costs of these evaluations are reported as kidney acquisition costs on TH A's cost report. Recipient A and Donor A do not match each other but both agree to participate in a KPD exchange.
- *TH B. Recipient B is a patient of TH B.* TH B evaluates two potential living donors for Recipient B before a donor, Donor B, is identified. The costs of these evaluations are reported as kidney acquisition costs on TH B's cost report. Recipient B and Donor B do not match each other but both agree to participate in a KPD exchange.
- *TH C.* Recipient C is a patient of TH C. TH C evaluates three potential living donors for Recipient C before a donor, Donor C, is identified. The costs of these evaluations are reported as kidney acquisition costs on TH C's cost report. Recipient C and Donor C do not match each other but both agree to participate in a KPD exchange.
- *TH D.* Recipient D is a patient of TH D. TH D evaluates three potential living donors for Recipient D before a donor, Donor D, is identified. The costs of these evaluations are reported as kidney acquisition costs on TH D's cost report. Recipient D and Donor D do not match each other but both agree to participate in a KPD exchange.

(Step 2), the KPD Match. Through the KPD exchange it is determined that Recipient A matches Donor C; Recipient B matches Donor D; Recipient C matches Donor A; and Recipient D matches Donor B.

(Step 3), After the KPD Match.

- Recipient C's TH requests Donor A's TH perform an additional test that was not included in Donor A's initial evaluation. Donor A's TH performs the additional test and bills Recipient's C's TH, charges reduced to cost, for the additional tests of Donor A. The amounts billed by TH A to TH C are included in TH C's MCR as organ acquisition costs for Recipient C.
- Donor B elects to travel to TH D for the procurement and any additional testing. (Note: The cost of travel for a living donor is not an allowable organ acquisition cost.)
- Donor A, Donor C, and Donor D remain at their original intended recipients' THs (TH A, TH C and TH D, respectively) where they were evaluated and where their organ procurement will occur.

(Step 4), Procuring, Packaging and Transporting the Kidneys.

- TH A procures Donor A's kidney and packages and transports it to TH C for Recipient C. TH A bills TH C, charges reduced to cost, for the reasonable costs associated with procuring, packaging and transporting the kidney as well as any additional testing requested by TH C that was not included in the initial evaluation of Donor A. Donor A's TH records these costs on its MCR as kidney acquisition costs and offsets any payments received from TH C against its kidney acquisitions costs.
- TH B does not procure a kidney. Donor B elects to travel to TH D for the procurement. TH D procures Donor B's kidney and records these costs on its cost report as kidney acquisition costs. TH B receives a kidney from TH D for transplant into recipient B. TH B records the amounts it pays to TH D on TH B's MCR as kidney acquisition costs.
- TH C procures Donor C's kidney and packages and transports it to TH A for Recipient A. TH C bills TH A, charges reduced to cost, for the reasonable costs associated with procuring, packaging and transporting the kidney as well as any additional testing requested by TH A that was not included in the initial evaluation of Donor C. Donor C's TH records these costs on its MCR as kidney acquisition costs and records any payments received from TH A on TH C's MCR to offset its kidney acquisitions costs.
- TH D procures Donor D's kidney and packages and transports it to TH B for recipient B. TH D bills TH B, charges reduced to cost, for the reasonable costs associated with procuring, packaging and transporting the kidney, as well as any additional testing requested by TH B that was not included in the initial evaluation of Donor D. Donor D's TH records these costs on its MCR as kidney acquisition costs and records any payments received from TH B on TH D's MCR to offset its kidney acquisitions costs. TH B records the amounts it pays to TH D for Donor D's kidney on TH B's MCR as kidney acquisition costs.

The following tables summarize the KPD exchange described previously.

TABLE 3—SUMMARY OF KIDNEY PAIRED DONATION EXCHANGE EXAMPLE

	TH A	TH B	TH C	TH D
Recipient	Recipient A	Recipient B	Recipient C	Recipient D
Number of evaluations	Evaluates 3 potential donors before Donor A is identified.	Evaluates 2 potential donors before Donor B is identified.	Evaluates 3 potential donors before Donor C is identified.	Evaluates 3 potential donors before Donor D is identified.
Donor	Donor A: Recipient A and Donor A do not match each other but agree to a KPD exchange.	Donor B: Recipient B and Donor B do not match each other but agree to a KPD exchange.	Donor C: Recipient C and Donor C do not match each other but agree to a KPD exchange.	Donor D: Recipient D and Donor D do not match each other but agree to a KPD exchange.
KPD match	Recipient A matches with Donor C.	Recipient B matches with Donor D.	Recipient C matches with Donor A.	Recipient D matches with Donor B.

[71] *https://www.livingdonorassistance.org/;* accessed on November 30, 2021.

TABLE 3—SUMMARY OF KIDNEY PAIRED DONATION EXCHANGE EXAMPLE—Continued

	TH A	TH B	TH C	TH D
Recipient	Recipient A	Recipient B	Recipient C	Recipient D
After the match	TH A performs additional tests and procures kidney from Donor A for TH C.	TH B does not procure kidney from Donor B for TH D. Donor B travels to TH D.	TH C procures kidney from Donor C for TH A.	TH D procures kidney from Donor D for TH B. Donor B travels to TH D for the kidney procurement.

TABLE 4—SUMMARY OF ACCOUNTING FOR KIDNEY PAIR DONATION EXAMPLE

	Accounting			
Cost of evaluations	$12,000 incurred by TH A	$9,000 incurred by TH B	$15,000 incurred by TH C	$20,000 incurred by TH D
Counting Medicare usable kidneys.	2 Medicare usable kidneys: 1 kidney procured/furnished and 1 kidney received/transplanted.	1 Medicare usable kidney: 1 kidney received/transplanted.	2 Medicare usable kidneys: 1 organ procured/furnished and 1 kidney received/transplanted.	2 Medicare usable kidneys: 1 kidney procured/furnished and 1 kidney procured/transplanted.
Donor costs associated with procuring, packaging and transporting the kidney to the recipient THs.	TH A bills TH C $18,000 for costs incurred to procure Donor A's kidney.	No bills sent to TH D	TH C bills TH A $10,000 for costs incurred to procure Donor C's kidney.	TH D bills TH B $14,000 for costs incurred to procure Donor D's kidney.
Recipient costs associated with procuring, packaging and transporting the kidney bill by Donor THs.	TH A receives a bill from TH C for $10,000 for costs incurred to procure Donor C's kidney.	TH B receives a bill from TH D for $14,000 for costs incurred to procure Donor D's kidney.	TH C receives a bill from TH A for $18,000 for costs incurred to procure Donor A's kidney.	No bills received from TH B. TH D claims all costs after initial evaluation for Donor B.
Kidney acquisition costs recorded on MCR.	$12,000 evaluation costs of TH A. $18,000 for costs billed to TH C. $10,000 billed from TH C	$9,000 evaluation costs of TH B. ..... $14,000 billed from TH D	$15,000 evaluation costs of TH C. $10,000 for costs billed to TH A. $18,000 billed from TH A	$20,000 evaluation costs of TH D. $14,000 for costs billed to TH B. $8,000 for costs incurred to procure Donor B's kidney at TH D.
Subtotal	$40,000	$23,000	$43,000	$42,000.
Offset on MCR amounts received from recipient TH. Amounts in ( ) denote a negative number.	($18,000) received from TH C.	No payment received from TH D.	($10,000) received from TH A.	($14,000) received from TH B.
Net cost recorded on MCR.	$22,000	$23,000	$33,000	$28,000.

In the proposed rule, we proposed to codify into the regulations the Medicare organ acquisition payment policy for kidney paired exchanges, as set forth in PRM section 3106. Consistent with this provision, we also proposed to add § 413.416(a) to new subpart L to specify that when a recipient and donor elect to participate in a kidney paired exchange, the costs of the initial living donor evaluations are incurred by the originally intended recipient's TH, regardless of whether the living donor actually donates to their originally intended recipient, a kidney paired exchange recipient, or does not donate at all. We also proposed to add § 413.416(b) to new subpart L to specify that in a kidney paired exchange, regardless of whether an actual donation occurs, once the donor and recipient are matched, any additional tests requested by the recipient's TH and performed by the donor's TH, are billed to the recipient's TH as charges reduced to cost (using the donor's TH's cost to charge ratio) and included as acquisition costs on the recipient TH's MCR. We also proposed to add § 413.416(c) to new subpart L to specify that in a kidney paired exchange, when a donor's TH procures and furnishes a kidney to a recipient's TH, all costs must be reasonable and necessary and (1) the donor's TH bills the recipient's TH the donor TH's charges reduced to cost or the TH's applicable SAC for the reasonable costs associated with procuring, packaging and transporting the kidney; (2) the donor's TH records these costs associated with procuring, packaging and transporting the kidney on its MCR as kidney acquisition costs and offsets any payments received from the recipient's TH against these kidney acquisition costs; and (3) the recipient's TH records as part of its kidney acquisition costs, the amounts billed by the donor's TH for the reasonable costs associated with procuring, packaging, and transporting the organ as well as any additional testing performed and billed by the donor's TH. We also proposed to add § 413.416(d) to new subpart L to specify that, in a kidney paired exchange—(1) when a donor's TH does not procure a kidney, but the donor travels to the recipient's TH for the organ procurement, the reasonable costs associated with the organ procurement are included on the MCR of the recipient's TH; and (2) travel expenses of the living donor are not allowable Medicare costs. In section II.C.2.c.(2). of this final rule with comment period, we finalized the proposal to add § 413.404(b)(2) to specify that when a TH/HOPO furnishes an organ to another TH or IOPO, it must bill the receiving TH or IOPO its SAC by organ type, or the hospital's standard departmental charges that are reduced to cost.

We did not receive comments on the proposal to codify Medicare's organ acquisition payment policy with respect to KPD transactions and as such, we are

finalizing these provisions as proposed in § 413.416.

l. Provisions Requiring Donor Community Hospitals to Charge OPOs Reasonable Costs, Charges Reduced to Cost

Medicare-certified hospitals that are not THs but collaborate with OPOs to procure organs from cadaveric donors for transplantation are hereinafter referred to as ''donor community hospitals''. To participate in the Medicare Program, donor community hospitals and THs have organ procurement responsibilities and must have an agreement with a designated OPO to timely notify the OPO of individuals whose death is imminent or who have died in the hospital (42 CFR 482.45(a)(1)). The OPO then implements its donation protocol and, when appropriate (after declaration of death and consent to donate), will arrange for the procurement of all medically suitable cadaveric donor organs for transplant, at the donor community hospital or TH. In this regard, donor community hospitals and THs may incur costs for services provided to cadaveric organ donors following declaration of death and consent to donate through the procurement of the organs (for example, use of the hospitals operating room, staff, and ventilators to maintain the viability of the cadaveric donor organs).

Currently, when a donor community hospital incurs costs for services provided to the cadaveric donor, as authorized by the OPO following the declaration of death and consent to donate, it bills the OPO its customary charges (not reduced to cost) or a negotiated rate. (PRM–1 section 3107). Donor community hospital billing procedures are described in IL 74–23, published July 1, 1974, which provides, ''where the excising hospital is not a TH, it will bill its customary charges for those services used in excising the cadaver kidney.'' Thereafter, the OPO includes the charges from the donor community hospital on its cost report as part of the OPO's organ acquisition costs. At the end of its accounting period, the TH/HOPO uses these amounts to calculate its renal and non-renal SAC amounts for the following year, and the IOPO uses these amounts to calculate its non-renal SAC amounts for the following year. Medicare contractor's also use these amounts to calculate the IOPO's kidney SAC for the following year.

When the IOPO furnishes an organ to a TH (or other OPO), the IOPO bills the TH (or other OPO) the IOPO's SAC for the specific organ type. Currently, when a TH/HOPO furnishes an organ to another TH or OPO, it must bill its SAC or its standard departmental charges reduced to cost. The OPO's SAC is a charge which reflects an average of the total actual costs the OPO incurs to furnish an organ and reflects amounts the OPO is charged by the donor community hospital for services the donor community hospital provides to cadaveric donors. THs then include these SACs they have paid to OPOs to procure organs as allowable acquisition costs in their bills to Medicare, which Medicare pays. Therefore, because the OPO's incurred costs are passed on to and paid by the TH, and because the TH then includes these amounts as organ acquisition costs on its cost report, this chain of incurred costs results in Medicare paying these donor hospital charges (that are not reduced to cost) when it reconciles the organ acquisition costs on the TH cost report.

Stakeholders have made CMS aware that some donor community hospitals are charging OPOs amounts that are in excess of reasonable costs for services provided to cadaveric organ donors, resulting in Medicare paying more than reasonable costs for the acquisition of cadaveric donor organs for transplant. In one instance, an OPO identified a donor community hospital in its designated service area that billed amounts in excess of reasonable costs. CMS reviewed the donor community hospital's bills to the OPO and the donor community hospital's MCR information to evaluate the costs associated with those charges. CMS computed, using the hospitals cost-to-charge ratios (CCR), that the charges billed by the donor community hospital in the amount of $194,000, equated to a cost of $11,000. Thus, the donor community hospital's actual costs were approximately 6 percent of their billed charges.

Organ acquisition costs are reimbursed under Medicare's principles of reasonable cost established under section 1861(v) of the Act. Donor community hospitals (and THs) are Medicare-certified hospitals and must follow Medicare's reasonable cost principles under section 1861(v) of the Act. Because the services donor community hospitals provide to cadaveric donors, and thus charge to OPOs, are included as organ acquisition costs on OPOs' cost reports, these charges are also subject to Medicare's principles of reasonable cost established under section 1861(v) of the Act, and 42 CFR 413.5 and 413.9.

In a 1978 final rule with comment, CMS similarly noted that THs have no basis for determining the reasonableness of the charges made by the OPO.[72] CMS observed that services furnished by OPOs, if they are not part of the transplant hospital, are billed to transplant hospitals, which pay the charges shown on the bill. The charges then become allowable costs of the hospitals.[73] When donor community hospitals charge OPOs amounts not reduced to costs, and the OPOs pay the charges shown on the bill, those charges become incorporated as organ acquisition costs to the TH and are subsequently shared by Medicare; thus, Medicare's reasonable cost principles applicable to organ acquisition costs are not observed. We note that organs recovered from donor community hospitals comprised 62 percent of all transplanted organs in 2017 and 2018.[74] We recognize that because THs bill the OPOs' charges to Medicare, Medicare is paying more than reasonable costs for these services that become organ acquisition costs.

Because these charges become allowable organ acquisition costs of the TH, we believe that donor community hospitals should be required to reduce their charges to cost for services provided to cadaveric donors and billed to OPOs, in accordance with reasonable cost principles given in section 1861(v) of the Act and in our regulations at 42 CFR 413.5 and 413.9. Doing so will result in conformance to Medicare reasonable cost principles, and result in reduced costs to the OPOs, subsequently reducing cadaveric donor SACs billed to THs or OPOs, which may benefit other payors, as well as Medicare. Donor community hospitals are reimbursed either a DRG payment by Medicare (if the patient is a Medicare beneficiary), or a payment from other payers, for services provided to a potential organ donor prior to declaration of death and consent to donate. For services provided after declaration of death and consent to donate, if our provision is implemented, donor hospitals will be reimbursed by OPOs for their reasonable costs in accordance with Medicare's principles of reimbursement. Therefore, a donor community hospital would see a reduction in reimbursement from OPOs, because the donor hospital was previously permitted to bill the OPO its customary charges or negotiated rates. However, donor community hospitals would still have their reasonable costs reimbursed.

We believe that an equitable and accurate methodology to reduce a donor

[72] 43 FR 58370 (December 14, 1978).

[73] Id.

[74] Scientific Registry of Transplant Recipients. Request for Information. Requested on 02/08/2021.

community hospital's charges to cost would be to use the most recently available hospital-specific CCR. Using the hospital-specific CCR would be unique to each donor community hospital and would more accurately compensate them for services provided to cadaveric organ donors, as opposed to using an alternative like the statewide CCR. Because contractors recalculate each hospital's specific CCR on an ongoing basis, whenever more recent cost report data is available, the hospital's specific CCR is arguably more accurate and more closely aligned with creating a uniform charge to cost structure.

One methodology we considered to reduce a donor community hospital's charges to cost was to require the donor community hospital to use its statewide average operating CCR and apply this statewide average CCR to its charges. The statewide average operating CCR is updated annually in the FY IPPS/LTCH rule and is a transparent source of data. We note that the statewide average operating CCR published in the FY 2021 IPPS/LTCH final rule was 0.272 for urban hospitals and 0.336 for rural hospitals. Using a statewide average CCR would even out any instances in which a hospital's operating costs fall above or below established parameters. However, because it is an average, it would not accurately represent the variability in actual hospital specific CCRs. Therefore, using a statewide CCR may not adequately serve the purpose of reducing charges to cost.

Stakeholders have suggested that some donor community hospitals are improperly billing OPOs for services provided to cadaveric donors *prior* to the declaration of death and consent to donate. This would be inappropriate because hospital services provided prior to declaration of death and consent to donate are billable to the donor's insurance in the same manner hospital services are billable to an individual receiving services, regardless of whether the payor is Medicare. We reiterate that when a donor community hospital or TH incurs costs for providing services to a cadaveric donor, as authorized by the OPO, only those costs incurred after the declaration of the donor's death and consent to donate are permitted to be billed to the OPO. The OPO must accept bills from donor community hospitals and THs for costs only incurred after the declaration of death and consent to donate. Contractors will review OPO cost reports to ensure that donor community hospitals and THs charge OPOs for cadaveric donor costs incurred after declaration of death and consent to donate.

We proposed to add § 413.418(a) in new subpart L, to specify that a donor community hospital (a Medicare-certified non-transplant hospital) incurs organ acquisition costs for donor organ procurement services, authorized by the OPO following declaration of death and consent to donate.

We proposed to add § 413.418(b) in new subpart L, to specify that for cost reporting periods beginning on or after October 1, 2021, when a donor community hospital incurs costs for services furnished to a cadaveric donor, as authorized by the OPO, the donor community hospital must bill the OPO its customary charges that are reduced to cost by applying its most recently available hospital specific cost-to-charge ratio for the period in which the service was rendered.

Comment: A few commenters suggested that if Medicare does not cover expenses prior to a donor's death, there would be uncompensated donor testing which may become the responsibility of the donor's family or other third-party payers.

Response: OPOs and THs are responsible for all costs for donor evaluation and medical management once declaration of death and consent for donation occurs. Generally, Medicare does not cover costs of services incurred for a potential organ donation as organ acquisition costs unless those costs occur after the declaration of death and consent to donate is obtained. Therefore, costs of services incurred for a potential organ donor prior to declaration of death and consent to donate must not be included on the OPO cost report.

Comment: A commenter supported our proposal and noted when entities continue to engage in improper billing they violate CMS reasonable cost principles, and drive up the overall cost of organ donation and procurement. Several commenters appreciated our concerns that some donor community hospitals bill OPOs more than cost for services provided to cadaveric donors and generally supported our proposal to require donor community hospitals to bill the OPO its customary charges reduced to cost for such services. However, some of these supporters that were OPOs indicated they have successfully negotiated competitive ''per-case'' rates with donor hospitals and stated there may be instances where OPOs have negotiated lower ''per-case'' rates than charges reduced to cost. These commenters suggested that our policy, if finalized as proposed, would unintentionally interfere with longstanding arrangements many OPOs have with donor community hospitals. Some supporters of our proposal underscored the importance of considering stakeholder input to create evidence-based policy.

Response: We appreciate the commenter's support for our proposal. We agree that when entities continue to engage in improper billing they violate CMS reasonable cost principles, and drive up the overall cost of organ donation and procurement. Our proposal was not intended to interfere with longstanding arrangements whereby OPOs and donor community hospitals have negotiated per-case rates that align with Medicare's reasonable cost principles. We agree that flexibility should be afforded to OPOs and donor community hospitals by allowing for alternative charge arrangements like per-case rates currently in place between some OPOs and donor community hospitals, however, as long as the amount is less than customary charges adjusted to cost.

Comment: Several commenters disagreed with our proposal and claimed it would increase administrative burden, which could delay payment. A commenter suggested to reduce donor community hospital administrative burden, donor community hospitals could continue normal billing practices, and either the OPOs or CMS could apply a cost to charge calculation using the public CCRs found in the IPPS Impact Files.

Response: We disagree with commenters' assertions that our proposal would increase administrative burden. We also disagree with the suggestion that OPOs or CMS should apply the CCR on behalf of the donor community hospitals. The current policy allows donor community hospitals to bill customary charges (or negotiated rates) to OPOs for services provided to the cadaveric donor; therefore, these hospitals have established billing practices in place and will not incur added burden as a result of our proposal. In addition, 42 CFR 413.24(f) requires all Medicare-certified donor community hospitals to file an MCR on an annual basis. Therefore, the information required to reduce charges to cost is readily available to donor community hospitals.

Comment: Some commenters claimed limiting amounts paid to donor community hospitals would limit the number of organs available for transplant. Another commenter stated when donor community hospitals charge, and OPOs pay amounts greater than cost, the policy provides a clear financial benefit to these hospitals. Another commenter stated because donor community hospitals are not

reimbursed for organ acquisition-related costs on the MCR they will have no incentive to support the costs associated with a deceased donor.

Several commenters suggested concern that some donor community hospitals may not work cooperatively with OPOs as a result of this proposal. One of these commenters acknowledged reports of some donor community hospitals billing ''outlandishly high charges'' for costs associated with organ recovery, but indicated their experience with donor community hospitals works because of negotiated acquisition fees in place. This commenter acknowledged that Medicare's CoPs require cooperation between hospital staff and OPOs, but questioned whether enforcement of those cooperation requirements is a priority.

Response: We appreciate commenters' concerns that the proposal would limit amounts paid to donor community hospitals. We acknowledge that when donor community hospitals bill, and OPOs pay, amounts greater than cost, the donor community hospital benefits financially. In the proposed rule, we noted that a donor community hospital would see a reduction in reimbursement from OPOs, because the donor community hospital was previously permitted to bill the OPO its customary charges or negotiated rates. However, donor community hospitals will still be paid for their services provided to potential donors, at amounts that recognize Medicare's reasonable cost principles.

In addition, donor community hospitals must work with OPOs per the Medicare requirements for CoPs at 42 CFR 482.45. These regulations require that donor community hospitals notify OPOs, in a timely manner, of individuals whose death is imminent or who have died in the hospital to assure that the OPO can determine medical suitability for organ donation. The regulations also require that the hospital work cooperatively with its designated OPO to educate staff on donation issues and maintain potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place. Our proposal to require donor community hospitals to charge OPOs amounts that are reduced to its cost does not impede hospitals' compliance with Medicare CoPs. Hospitals will still be paid for their services provided to potential donors, at amounts that recognize Medicare's reasonable cost principles. As such, we believe that our proposal should not impact the number of organs available for transplant or cooperation between OPOs and donor community hospitals because OPOs and donor community hospitals must continue to work together, as required under Medicare CoPs, to procure all available organs for transplant.

Comment: Many commenters suggested alternatives to our proposal to require donor community hospitals to bill OPOs charges reduced to cost. These commenters suggested that CMS require donor community hospitals to bill OPOs an amount no more than customary charges adjusted to cost, but allow for alternative charge arrangements like per-case rates currently in place between some OPOs and donor community hospitals, as long as the amount is less than customary charges adjusted to cost. A few commenters suggested CMS establish a maximum price ceiling instead of a universal price so that these per-case rates, often perceived to be more competitive, can remain in place. A commenter requested we temporarily withdraw the proposal and develop a donor community hospital SAC methodology that would permit such hospitals to charge (and OPOs to pay) rates above actual, reasonable cost. A few commenters suggested CMS work with stakeholders to develop a model to account for the cost of delayed or canceled operating room procedures and use this model when an OPO and a donor community hospital do not have a negotiated a standard acquisition charge. Finally, several commenters requested our proposals be delayed to allow time for an impact analysis.

Response: We appreciate commenters' suggestions to withdraw the proposed policy and develop a SAC for donor community hospitals that would permit OPOs to pay charges greater than cost, but respectfully disagree. The SAC generally represents the average of the total actual costs associated with procuring either cadaveric donor organs or living donor organs and is based on Medicare's reasonable cost principles, which do not allow for payment of amounts greater than reasonable cost. We believe that flexibility should be afforded to OPOs and donor community hospitals and THs by allowing for alternative charge arrangements like per-case rates currently in place between some OPOs and donor community hospitals, as long as the amount is less than customary charges adjusted to cost. Because of this flexibility, we do not believe that we need to develop a model, as commenters suggest, to account for the cost of delayed or canceled operating room procedures and to use this model when an OPO and a donor community hospital do not have a negotiated standard acquisition charge. We also do not believe that our proposals should be delayed so that an impact analysis can be conducted. As we discussed in the proposed rule, we believe the impact is not estimable because we do not have information to calculate the effects on revenue and costs to donor community hospitals, OPOs, or transplant hospitals.

Comment: A few commenters suggested that CMS should specify that the proposal to require that donor community hospitals bill OPOs customary charges that are reduced to cost should not apply only to donor community hospitals, but also to THs that bill OPOs for services provided to cadaveric donors. A commenter claimed our proposal is inconsistent with past position on hospitals maintaining uniform and customary charge structures that apply universally to all payers and requested we withdraw our proposal.

Response: We agree that THs provide services to cadaveric donors, placing them in a similar situation as donor community hospitals when billing amounts to OPOs for services provided to cadaveric donors following the declaration of death and consent to donate, as authorized by the OPO. We believe that a TH must bill the OPO its customary charges that are reduced to cost by applying its most recently available hospital-specific CCR for the period in which the service was rendered, or a negotiated rate. We note that charges for services provided to cadaveric donors become organ acquisition costs, and payment for such aligns with Medicare's reasonable cost principles under which organ acquisition costs are paid and does not run afoul of CMS requirements for hospitals to maintain uniform and customary charge structures. As such, we do not believe it is necessary to withdraw our proposal.

Comment: Some commenters suggested CMS institute an oversight mechanism for enforcing our proposal, as they perceive no requirement for donor community hospitals to negotiate rates with OPOs.

Response: Providers under the Medicare program are required to submit Medicare cost reports on an annual basis 42 CFR 413.24(f). We believe that Medicare contractors' review and audit of hospitals' submitted cost reports serve as an existing oversight mechanism for enforcing our proposal.

Comment: Some commenters requested specific instructions be issued to hospitals for the appropriate billing of their charges reduced to cost, and questioned which hospital CCRs should

be used in the calculation, and whether it should be based on final cost reports or on interim cost reports. Other commenters questioned whether OPOs will be required to validate the CCRs used by hospitals, where CMS will publish the hospital specific files, or if hospitals will be required to furnish their hospital specific CCR in cases where they have case rates or flat rates with the OPO. A commenter stated that use of the most recently available MCR could understate costs due to increasing healthcare costs. A commenter suggested, when the most recently available MCR is used, an update factor should be applied to ensure the cost represents the costs for the period in which the service was actually provided. Another commenter questioned whether hospitals should bill OPOs for physician professional fees at cost, or whether OPOs should pay physician charges based on the Medicare physician fee schedule to ensure that OPOs are not overpaying hospitals for physician services.

Response: We are clarifying that a donor community hospital must use the most recently available hospital specific CCR, included in the provider-specific file published on the CMS website, [75] for the period in which the service was rendered. The hospital-specific CCR is the same CCR that is used in the IPPS outlier calculation. A donor community hospital must provide, upon request from the OPO or TH, its hospital-specific CCR for review, or comparison in cases where they have case rates or flat rates with the OPO. If the donor community hospital or TH believes its most recently available CCR does not convert charges to reflect its actual cost, we believe instead of applying an update factor, it would be reasonable for the hospital to follow the procedures outlined in the Medicare Claims Processing Manual, (CMS Pub. 100–04), chapter 3, section 20.1.2.1. for use of an alternative CCR. Finally, we appreciate the commenters' concern about OPOs overpaying hospitals for physician services; however, we believe that OPOs either employ or contract with physicians to provide services in a donor community hospital. In addition, our proposal only addressed charges as they relate to hospital services provided to cadaveric donors.

After consideration of the public comments we received, we are finalizing our proposal with modifications based on comments received to specify at § 413.418(a) in new subpart L, that a donor community hospital (a Medicare-certified non-transplant hospital) and a transplant hospital incur organ acquisition costs for donor organ procurement services, authorized by the OPO following declaration of death and consent to donate. We are also finalizing our proposal with modifications, to specify at § 413.418(b) that for cost reporting periods beginning on or after the effective date of this final rule with comment period, when a donor community hospital or a transplant hospital incurs costs for services furnished to a cadaveric donor, as authorized by the OPO, the donor community hospital or transplant hospital must bill the OPO the lesser of its customary charges that are reduced to cost by applying its most recently available hospital specific cost-to-charge ratio for the period in which the service was rendered, or a negotiated rate.

m. Revisions, Technical Corrections, and Conforming Changes to 42 CFR Part 412, Subparts A, E, G, and H and to Part 413, Subparts A, C, and H

(1) Conforming Changes to Terminology in 42 CFR Parts 412 and 413

In section X.B.2.a.(1). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule and in section II.C.2.a.(1). of this final rule with comment period, we noted terminology differences in the use of ''transplantation center'', where the regulations in 42 CFR part 412, subparts A, E, G, and H and in Part 413, subparts A, C, and H use the term to mean an organ-specific transplantation program that is within a TH. We proposed to conform the language in the regulation text to the terminology used in the CoPs at § 482.70 by replacing the term ''transplantation center'' and its various permutations with the term ''transplant program'' and its various permutations. We proposed to make this conforming change in the text of the following regulations: §§ 412.1(a)(1)(ii), 412.2(e)(4), 412.71(b)(3), 412.90(d), 412.100 (in the title and in the text at §§ 412.100(a)(1)), 412.113(d), 412.116(c), and 413.40(a)(3). We also proposed to update the terminology to replace ''organ procurement agency'' and its various permutations with ''organ procurement organization'' and its various permutations. Further, we proposed to replace the acronym ''OPAs'' with ''OPOs''. We proposed to make these terminology changes to the regulation text at §§ 412.100(b) and 413.1(a)(2)(v) to conform to the terminology used in the CoPs found in 42 CFR part 482. Finally, we proposed to change ''renal'' to ''kidney'' in §§ 412.71(b)(3), 412.90(d), in the title and paragraph (a) of § 412.100, and in § 412.116(c), to conform to the terminology used in the CoPs at § 482.104.

We did not receive comments on these proposals and are finalizing these provisions as proposed.

(2) Revisions, Technical Corrections, and Conforming Changes to § 412.100

In the proposed rule, we proposed to revise the text currently found in § 412.100(a) and (b) to change ''expenses'' to ''costs'' and to remove the word ''estimated'' from § 412.100(a)(1). We also proposed to make a technical correction to remove from § 412.100(a)(1) cross-references to CoPs which no longer exist, and replace them with § 482.104, and proposed to add language to clarify that CMS adjusts inpatient prospective payment system (IPPS) rates for inpatient operating costs. We proposed to revise § 412.100(a)(1) to state that CMS adjusts the inpatient prospective payment system (IPPS) rates for inpatient operating costs determined under subparts D and E of this part for hospitals with approved kidney transplant programs (discussed at § 482.104) to remove the net costs associated with kidney acquisition.

Additionally, we proposed to revise § 412.100(a)(2) to clarify the language, and to specify that Medicare payment for kidney acquisition costs includes only those costs for kidneys transplanted into Medicare beneficiaries. We proposed to revise § 412.100(a)(2) to specify the following:

- Payment for Medicare kidney acquisition costs, as set forth in subpart L of part 413 of this chapter, is made on a reasonable cost basis apart from the prospective payment rate for inpatient operating costs.
- IPPS payment to the hospital is adjusted in each cost reporting period to reflect an amount necessary to compensate the hospital for reasonable costs of Medicare kidney acquisition.

In section X.B.2.b.(1). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to revise § 412.100(b) by revising and relocating the list of organ acquisition costs given in that paragraph and adding the list as paragraph (b) in proposed § 413.402 of new subpart L. Further, we proposed to revise § 412.100(b) to make it clearer that kidney acquisition costs must be incurred. Finally, we proposed to revise § 412.100(b) to add language that the items and services covered as kidney acquisition costs are specified in § 413.402(b).

[75] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspMedicareFeeSvcPmtGen/psf_text.*

We did not receive comments on the proposals made in section X.B.2.m.(2). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, and are finalizing our provisions as proposed.

(3) Revisions and Conforming Changes to 42 CFR 412.113(d)

In addition to the conforming change discussed in section X.B.2.m.(1). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to revise the regulation text at § 412.113(d) to reference the organ acquisition policies given in new subpart L of part 413, rather than to maintain the existing cross-reference to the definition of organ given in § 486.302.

We did not receive comments on this proposal and are finalizing the provision as proposed.

(4) Technical Corrections and Conforming Changes to § 413.1

In addition to the conforming change discussed in section X.B.2.m.(1). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we revised the text in § 413.1(d)(2)(i) to put it into list form. We also proposed to revise the text related to kidney acquisition costs to refer to organ acquisition costs as specified in part 413 subpart L.

We did not receive comments on this proposal and are finalizing the provision as proposed.

(5) Revisions to 42 CFR 413.40(a)(3)

In addition to the proposed conforming changes discussed in section X.B.2.m.(1). of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we set forth a technical correction and a revision to paragraph (a)(3) of § 413.40. We proposed to revise the regulation text that references heart, kidney, and liver acquisition costs to refer to organ acquisition costs as specified in part 413 subpart L so that the language reflects all solid organs for which Medicare covers organ acquisition costs and directs readers to the organ acquisition cost regulations in part 413, subpart L.

We did not receive comments on this proposal and are finalizing the provision as proposed.

(6) Regulatory Changes to § 413.200

We proposed to remove the regulation found at 42 CFR 413.200 specifying payment of independent organ procurement organizations and histocompatibility laboratories. We proposed to add § 413.400 to contain revised text from § 413.200(b), and to add § 413.420 to contain the remaining regulation text from § 413.200 (a) and (c) through (g), along with a revised title, so that the content of § 413.200, with revisions, is located with other regulations specific to organ acquisition in part 413, new subpart L. We proposed to make a technical correction or revisions to two of the three definitions found in § 413.200(b), as described in section II.C.2.a.(2). of this final rule with comment period. We proposed to add these definitions to proposed § 413.400, as described in section II.C.2.a.(2). of this final rule with comment period.

We proposed to relocate and revise the regulation title and regulation text currently existing in § 413.200 in paragraphs (a), and (c) through (g), by adding § 413.420 to specify payment to independent organ procurement organizations and histocompatibility laboratories for kidney acquisition costs and by adding paragraphs (a), and (c) through (g) with the text from those same paragraphs in § 413.200. We proposed to make conforming changes to the regulation text in § 413.420(a), and (c) through (g), to distinguish independent OPOs (IOPOs) from all OPOs where appropriate, in accordance with the proposed definition of IOPO in § 413.400. We also proposed to add paragraph (b) to § 413.420 to provide a cross-reference to the definitions in § 413.400 of new subpart L. Therefore, the proposed new § 413.420 would maintain the same paragraph structure as the existing § 413.200. Finally, we proposed minor revisions to clarify the regulation text, including changing language from passive to active tense, changing verbs from future tense to present tense, and editing to improve readability.

We did not receive comments on these proposals and are finalizing the provisions as proposed.

3. Solicitation of Comments Regarding Surgeon Fees for Cadaveric Donor Excisions

Since 1987, we have limited the amount an OPO may reimburse a physician for cadaveric kidney donor retrieval services. Chapters 27 and 31 of the PRM limit the physician payment for cadaveric kidney retrieval to $1,250 per donor (one or two kidneys). The history behind the limitation on physician payment may be based on a July 1974 $400 physician services limitation on excising kidneys in community hospitals that do not participate in Medicare, which was noted in a Part A Intermediary Letter (IL No. 74–23, July 1974); it may also be based in part on the 1983 median cost paid by OPOs for surgical excision of cadaveric kidneys, which was approximately $800.[76] Although the payments made to physicians for organ retrieval services associated with other types of organ transplants have increased, cadaveric kidney retrieval rates have remained capped at $1,250. We have received several requests to change the amount we pay for cadaveric kidney retrievals. In the CY 2009 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009 (hereafter, Physician's Fee) proposed rule (73 FR 38580 and 38581), we solicited public comments and data that are reflective of organ retrieval service costs for all types of organs. At that time, we did not have data upon which to base a change in payment. We stated that we may use this information to determine the extent to which a recalculation of the payment for cadaveric organ retrieval services performed by a physician is warranted and to inform any future rulemaking on this subject. We received four timely public comments in response to our request for information and data for use in updating the organ retrieval physician payment amount included in organ acquisition costs, which were discussed in detail in the CY 2009 Physicians Fee Schedule final rule (73 FR 69864). However, we did not receive any data that would be useful in evaluating the appropriateness of the $1,250 per donor surgeon fee limit for cadaveric kidney retrievals.

For this final rule, we used 2017 cost report data from 48 OPOs to calculate a surgeon fee cost per local kidney for each provider, by dividing the kidney surgeon fee costs reported on Worksheet A–2, line 13, column 3 of the MCR by the number of local kidneys reported on Worksheet S–1, Part 1, Line 1, column 1 of the MCR. Excluding three providers with extremely low surgeon fees per local kidney (ranging from $0 to $231), the average surgeon fee cost per local kidney was $745. These provider-reported data suggest that the $1,250 limit on surgeon fees for cadaveric donor kidney retrievals is sufficient and allows for some higher cost excisions. However, we have received comments suggesting that this limit needs to be reconsidered.

While we did not propose to change the physician payment limit for cadaveric kidney retrieval, we solicited information on the physician effort and resources required to procure a

[76] Organ Transplants: Hearings before the Subcommittee on Investigations and Oversight, of the House Committee on Science and Technology. 98th Cong. 43 (1983) (testimony of Carolyne K. Davis, Ph.D., Administrator, Health Care Financing Administration).

cadaveric kidney for transplantation. Specifically, we solicited data or other information on surgical time, dry runs (number and percentage of retrievals in which an organ is not recovered), travel and wait times, as well as the incremental time required for extended criteria donors and donors after cardiac death. Additionally, we solicited resource information to determine the difference in procuring one kidney or a pair of kidneys from a single donor. We indicated in the proposed rule that the comments we received may inform development of future proposals related to surgeon fee payment for organ retrieval from cadaveric donors.

Comment: Commenters were generally appreciative of this comment solicitation. A commenter did not support increasing surgeon fees for cadaveric kidney removal, and stated that CMS should consider whether an increase to surgeon fees and the additional cost burden to the Medicare Trust Fund would result in an increase in the number of kidneys available for transplant. This commenter stated that many existing OPO practices already maximize kidney donation within the current payment limit and without incurring additional costs, and those practices should not be disrupted.

Some commenters supported increasing surgeon fees. Most of these commenters stated that the current limit of $1,250 is inadequate relative to the surgical, travel, dry run, and wait times. Some commenters cited increased travel costs resulting from new kidney allocation policies, and medical and technological advancements in donor management which have added to the cost of surgical procurement. A commenter noted that procuring marginal kidneys increases the complexity of organ recovery and the frequency of intra-operative findings that result in the abandonment of the effort. Some commenters added that DCD procurements add complexity to the procurement process and require surgeons to learn new skills. A commenter stated that the entire vasculature (including the aorta and vena cava) and en-bloc kidneys are dissected out and removed from the donor body, and then separated outside.

A commenter stated that an OPO sometimes pays more than $1,250 to ensure surgeons are readily available to excise kidneys; the commenter stated amounts over $1,250 are not reimbursable and must be absorbed by other non-renal or tissue revenue, with this cost shift increasing SAC fees for non-renal organs, or, when covered by tissue revenue, requiring the OPO to pay for costs that are a result of services provided to a Medicare beneficiary. This commenter encouraged CMS to ensure that the costs attributable to Medicare beneficiaries are appropriately covered.

A commenter questioned if the cadaveric kidney retrieval cap of $1,250 also applies to the transplant hospitals, and if so, how the retrieval cap applies when multiple organs are excised. This commenter also questioned if CMS has an established cap on surgeon fees for the excision of other organs.

Another commenter stated that CMS' use of 2017 cost report data is flawed, as most OPOs only contract and pay their kidney surgeons $1,250 per donor (due to Medicare's limitation), so the cost report worksheet A–2 data would only reflect the limitation on surgeon fees as cost, and the average kidney surgeon fee cost per kidney should be around $1,250.

A few commenters suggested that CMS formally survey transplant programs to collect the data necessary to rebase payments for this service. Another suggested CMS establish an annual process to solicit stakeholder input to update pricing. A commenter recommended that CMS apply at least an inflationary increase to the historical $1,250 rate while continuing to collect community data to support an updated fee. Another commenter welcomed additional opportunities for OPOs to collect and provide relevant data beyond this 60-day comment window.

Response: We appreciate these comments, and may consider them if we undertake future rulemaking related to surgeon fees for recovering cadaveric kidneys.

III. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the FY 2022 IPPS/LTCH PPS proposed rule, we solicited public comment on the following provision of this final rule comment period that contain information collection requirements (ICRs).

As discussed in section II.B.3. of this final rule with comment period, teaching hospitals would be able to submit electronic applications to CMS for resident slot increase requests. The burden associated with these requests is captured in an information collection request currently available for public review and comment. The 60-day notice published on October 22, 2021 (86 FR 58664). We note that the application included in this information collection has yet to be approved. Comments can be submitted as part of October 22, 2021 60-day notice or as part of the subsequent 30-day **Federal Register** notice. We will review and respond to any comments received on either notice.

IV. Regulatory Impact Analysis

A. Statement of Need

1. Changes to the IME and Direct GME Payments

This final rule with comment period is necessary in order to make Medicare payment and policy changes to the statutory methodology for determining payments to hospitals for the direct costs of approved GME programs and the IME adjustment under the IPPS for hospitals that have residents in an approved GME program, as described in more detail in section IV.C. of this final rule with comment period. The primary objective of the IPPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

In this final rule with comment period, we are finalizing policies to implement sections 126, 127, and 131 of the CAA of 2021. Section 126 makes available 1,000 new Medicare-funded GME positions (but not more than 200 new positions for a fiscal year), to be distributed beginning in FY 2023, with priority given to hospitals in 4 statutorily-specified categories. Section 127 of the CAA makes statutory changes relating to the determination of both an urban and rural hospital's FTE resident limit for direct GME and IME payment purposes with regard to residents

training in an accredited rural training track, and to the 3-year rolling average used to calculate payments for these hospitals. Section 131 of the CAA makes statutory changes to the determination of direct GME PRAs and direct GME and IME FTE resident limits of hospitals that hosted a small number of residents for a short duration. We expect these changes will make appropriate Medicare GME payments to hospitals for Medicare's share of the direct costs to operate the hospital's approved medical residency program, and for IPPS hospitals the indirect costs associated with residency programs that may result in higher patient care costs, consistent with the law.

We expect that these changes will ensure that the outcomes of these Medicare payment policies are reasonable and provide equitable payments, while avoiding or minimizing unintended adverse consequences.

2. Changes to the Organ Acquisition Payment Policies

In the FY 2022 IPPS/LTCH/PPS proposed rule, we proposed Medicare payment and policy changes to the methodology for counting Medicare organs by transplant hospitals, and Medicare kidneys by OPOs, for calculation of Medicare's share of organ acquisition costs, however, in this final rule with comment period, we are not finalizing the proposed organ counting policy, and may revisit the policy in future rulemaking. Therefore, the Medicare organ counting policy is not addressed in the regulatory impact analysis of this final rule with comment period.

In this final rule with comment period, we are finalizing certain longstanding organ acquisition payment policies to better support organ availability and transplantation. We are finalizing a policy related to amounts billed to OPOs for organ acquisition costs when a donor community hospital or transplant hospital incurs costs for services furnished to a cadaveric donor, to ensure that billing is in accord with reasonable cost principles. We are also finalizing existing payment policies to clarify and codify definitions, organ acquisition costs, and examples of items or services that are not organ acquisition costs; to allow certain additional registry fees and transportation costs; to codify existing policies related to living organ donor complications and clarify accounting and payment methods; to codify existing policies related to standard acquisition charges, acquisition of pancreata for islet cell transplants, Medicare as a secondary payor, kidney-paired donations, and payment to independent OPOs and histocompatibility laboratories for kidney acquisition costs. We expect these codifications will provide greater understanding of organ acquisition payment policies to the organ procurement and transplant community, and that our allowing certain additional costs will support organ transplantation and improve health equity. We expect these changes will result in clarity and consistency with Medicare's reasonable cost principles.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 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, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action(s) and/or with economically significant effects ($100 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of the rulemaking.

The analysis in this RIA, in conjunction with the remainder of this document, demonstrates that this final rule with comment period is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This final rule with comment period would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget has reviewed this final rule with comment period.

C. Detailed Economic Analysis

1. Effects of the Changes to IME and Direct GME Payments

The CAA of 2021 contained 3 provisions affecting Medicare direct GME and IME payments to teaching hospitals. Section 126 of the CAA makes available 1,000 new Medicare-funded GME positions, with 200 slots to be distributed in 5 rounds over 5 years starting in FY 2023, with priority given to hospitals in 4 categories. Section 127 of the CAA, effective for cost reporting periods beginning on or after October 1, 2022, makes changes relating to the determination of both an urban and rural hospital's FTE resident limit for direct GME and IME payment purposes with regard to residents training in an accredited rural training track, and the application of the 3-year rolling average to the payment calculation of these hospitals. Section 131 of the CAA makes changes to the determination of direct GME PRAs and direct GME and IME FTE resident limits of hospitals that hosted a small number of residents for a short duration, based on new programs started on or after enactment (December 27, 2020) and 5 years after (December 26, 2025). We provided details for implementing these 3 GME CAA provisions in section II.B. of this final rule with comment period. Following is a table showing the

estimated cost of implementation of these 3 GME CAA provisions:

TABLE 5—COST IMPACT OF CAA 2021 GME PROVISIONS

[In $millions]

FY	Section 126	Section 127	Section 131
2021	0	0	10
2022	0	0	30
2023	10	0	60
2024	60	10	90
2025	120	10	130
2026	180	10	150
2027	240	20	170
2028	290	20	180
2029	300	20	180
2030	310	20	190
2031	320	20	190

In summary, the Office of the Actuary estimates an increase of $10 million in Medicare payments to teaching hospitals for FY 2021, an increase in Medicare payments to teaching hospitals of $860 million for FYs 2022 through 2026 (over 5 years). In total, for FYs 2021 through 2031, Medicare payments to teaching hospitals are estimated to increase by $3.30 billion.

2. Effects of the Organ Acquisition Payment Policy

In section X.C.2. of the preamble of the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to codify into the Medicare regulations some longstanding Medicare organ acquisition payment policies, with clarifications where necessary, and to codify some new organ acquisition payment policies. In section II.C.2.a of this final rule with comment period, we discuss clarifications and codification of longstanding definitions related to organ acquisition. These final policies are not expected to have an impact on expenditures because the finalized policies pertain to changes to definitions and usage of consistent terminology. In section II.C.2.b of this final rule with comment period, we discuss the revisions to and codification of longstanding policies related to items or services that are organ acquisition costs, which we are modifying to allow certain additional organ recipient registry fees and cadaveric donor transportation costs. To the extent that these provisions have an impact on expenditures, that impact is not estimable because we do not have information to calculate the change in registry fee costs or transportation costs. In sections II.C.2.c. and II.C.2.d. of this final rule with comment period, we discuss our final policies related to standard acquisition charges and outpatient costs and laboratory services related to organ acquisition, however, these final policies are not expected to have an impact on expenditures.

In section II.C.2.e. this final rule with comment period, we also discuss revisions to and codification of longstanding policies related to Medicare coverage of living donor complications. To the extent that these provisions have an impact on expenditures, that impact is not estimable because we do not have cost data pertaining to non-renal living donors to calculate the increase in cost from codifying policies specifying reporting and payment of costs for non-renal living donor complications. In sections II.C.2.f. and II.C.2.g. of this final rule with comment period, we discuss final policies related to services to transplant recipients and the codification of a statutory policy related to pancreatic islet cell transplants, which are not expected to have an impact on expenditures.

In section II.C.2.h. of this final rule with comment period, we discuss the organ counting policy, however, we are not finalizing our proposed policy and as such, there are no impacts on expenditures. In section II.C.2.i. of this final rule with comment period, we discuss final policies related to intent to transplant, and counting en bloc, research, and discarded organs which are not expected to have an impact on expenditures. In sections II.C.2.j. and II.C.2.k. of this final rule with comment period, we discuss the codification of longstanding organ acquisition policies related to Medicare as a secondary payor and accounting for kidney-paired donations, respectively, which are not expected to have an impact on expenditures.

Additionally, in section II.C.2.l. of this final rule with comment period, we discuss finalized policy codifications for donor community hospitals' (Medicare-certified non-transplant hospitals) and THs' charges for services provided to cadaveric donors. To the extent that these provisions have an impact on expenditures, that impact is not estimable because we do not have information, such as the cost of services and number of cadaveric donors to whom services are provided to calculate the effects on donor community hospitals, or transplant hospitals for services provided to organ procurement organizations. Based on the Scientific Registry of Transplant Recipient (SRTR) data, we recognize that organs recovered from donor community hospitals comprised 62 percent of all transplanted organs in 2017 and 2018.[77] Under the current policy, donor community hospitals bill customary charges or negotiated rates and not charges reduced to cost. Because our final policy requires donor community hospitals and THs to bill the lesser of charges reduced to cost or a negotiated rate, we anticipate a cost savings to the Medicare Trust Fund.

In section II.C.2.m. of this final rule with comment period, we finalized technical corrections, clarifications, conforming changes, and redesignations in the regulations, which are not expected to have an impact on expenditures. Finally, in section II.C.3. of this final rule with comment period, we solicited comments on the existing cap on surgeon fees for cadaveric kidney excisions and provided a summary of the comments received; there is no expected impact of the comment solicitation.

Comment: With regard to the organ counting proposal, some commenters believed that Medicare's impact

[77] Scientific Registry of Transplant Recipients. Request for Information. Requested on 02/08/2021.

estimate was underestimated and imprecise when using SRTR payor data to estimate organs transplanted into Medicare beneficiaries. One commenter suggested we calculate and use an ''in-house'' Medicare ratio for TH/HOPOs, as a proxy to apply to the number of organs the TH/HOPO furnishes to other hospitals or OPOs which are transplanted into Medicare beneficiaries. Other commenters requested that Medicare study and publish a hospital specific impact analysis resulting from these proposals. Some commenters also raised concerns about the effects of this proposal on children's transplant hospitals.

Response: We thank commenters for bringing to our attention the need for additional analyses to better understand the effects of the Medicare usable organ and kidney counting proposal. Our proposed rule impact estimation methodology determined Medicare organ acquisition costs using 2018 cost data by organ type, by multiplying total acquisition costs by the SRTR payor data ratio for Medicare as the payor. We summed these organ-specific Medicare organ acquisition costs, and compared that total with the total Medicare organ acquisition costs calculated using the same methodology, but using the Medicare ratio from the cost report data rather than the SRTR ratio; the difference between the two Medicare organ acquisition cost amounts was the estimated savings for a single year.

After consideration of the public comments we received, we are not finalizing our organ counting proposals, and may revisit this proposal in future rulemaking.

D. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed or final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we believe that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcomed any public comments on the approach in estimating the number of entities that would review the proposed rule. We did not receive any public comments specific to our solicitation.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought public comments on this assumption. We did not receive any public comments specific to our solicitation.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $114.24 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it would take approximately 4.16 hours for the staff to review half of this final rule with comment period. For each entity that reviews the rule, the estimated cost is $475.24 (4.16 hours × $114.24). Therefore, we estimate that the total cost of reviewing this rule is $270,886.80 ($475.24 × 570).

E. Alternatives Considered

This final rule with comment period contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the finalized policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

1. Alternatives Considered for Distribution of Additional Residency Positions Under the Provisions of Section 126 of the CAA

Section 126(a) of the CAA amended section 1886(h) of the Act by adding a new section 1886(h)(9) of the Act requiring the distribution of additional residency positions to qualifying hospitals. Section 1886(h)(9)(A) of the Act requires that for FY 2023, and for each succeeding fiscal year until the aggregate number of FTE residency positions distributed is equal to 1,000, the Secretary shall initiate separate rounds of applications from hospitals for these additional residency positions.

After consideration of public comments, we are finalizing our proposal with modifications, that applicant hospitals are eligible for distribution of residency positions under section 126 if they meet the definition of any one or more of the statutory categories, Category One, Category Two, Category Three, or Category Four, as described in section II.B.3. of this final rule with comment period. Based on the residency training program for which the hospital is applying, the hospital will choose, if applicable, either a geographic or population HPSA where residents spend at least 50 percent of their training time. Hospitals will attest to meeting this 50 percent training criterion.

The HPSA scores associated with the geographic or population HPSAs chosen by hospitals that qualify under the aforementioned criteria will be ranked from highest to lowest and the 200 residency positions available for each FY will be prioritized in this manner, with each applicant hospital receiving up to 5.0 FTEs based on the length of the program associated with the hospital's application.

We considered alternative approaches for distribution of additional residency positions under the provisions of section 126 of the CAA. An alternative we considered was to distribute 200 additional residency positions for FY 2023 entirely among hospitals that qualify in Category One, Category Two, Category Three, and/or Category Four, with higher priority given to applications from hospitals that qualify in more categories. We would distribute 1.0 FTE to each hospital that qualified under all four categories, prorating only in the event that the number of hospitals that qualified under all four categories exceeds 200. However, given that we believe the additional residency positions distributed under section 126 of the CAA should be consistent with the Administration's goal of advancing health equity in underserved communities, we believe prioritizing applications based on HPSA scores is a feasible means to achieve this goal. Therefore, we are not finalizing our proposed alternative.

2. Alternatives Considered for Counting Organs Used To Determine Medicare's Share of Organ Acquisition Costs

After consideration of public comments, we considered two alternatives for counting organs used to determine Medicare's share of organ acquisition costs: (1) Withdrawing the proposal; or (2) finalizing the proposal but with a delay or a delay with a transition. Although we believe our proposed organ counting policy is appropriate and consistent with Medicare's anti cross-subsidization principles at section 1861(v) of the Act, and our regulations at 42 CFR 413.5, which do not permit the Medicare program to bear the costs of non-Medicare patients, we have decided to not finalize the proposal to allow more time to better understand concerns that

commenters have raised. We would like more time to thoroughly evaluate some of the concerns raised by commenters, such as those related to tracking the payor status of the organ recipients, to ensure that the policy can be operationalized by all OPOs and THs without a disruption to the transplantation ecosystem. We also recognize commenters' concerns about other changes occurring in the transplantation ecosystem which compete for time and resources, such as adapting to the new organ allocation system and initiatives to increase kidney transplantation. Therefore, we decided we are not finalizing our proposal at this time, and may revisit this proposal in future rulemaking.

F. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement in Table 6 showing the classification of the impact associated with the provisions of this final rule with comment period as they relate to Medicare GME payments to hospitals from FY 2021 to FY 2031. Table 6 provides our best estimate of the change in Medicare payments to providers as a result of the changes to the Medicare GME payments presented in this final rule with comment period. All expenditures are classified as transfers to Medicare providers.

TABLE 6—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM FY 2021 TO FY 2031

Category	7% Discount rate	3% Discount rate
Annualized Monetized Transfers	$245.25 Million	$277.30 Million.
From Whom to Whom?	Federal Government to Medicare Providers (Teaching Hospitals).	

G. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business. Table 7 details the size standards for those industries that may be affected by this rule, though we expect that General Medical and Surgical Hospitals would be most affected.

TABLE 7—SIZE STANDARDS BY AFFECTED INDUSTRY

NAICS Code	NAICS industry description	Size standard (in millions)
622110	General Medical and Surgical Hospitals	$41.5
622210	Psychiatric and Substance Abuse Hospitals	41.5
622310	Specialty (except Psychiatric and Substance Abuse) Hospitals	41.5

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Because all hospitals are considered to be small entities for purposes of the RFA, the hospital impacts described in this final rule with comment period are impacts on small entities. Individuals and States are not included in the definition of a small entity. MACs are not considered to be small entities because they do not meet the SBA definition of a small business.

HHS's practice in interpreting the RFA's reference to a ''significant economic impact on a substantial number of small entities'' is to consider effects economically ''significant'' if greater than 5 percent of small providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. Based on our analysis described in section IV.C. this final rule with comment period, we believe that the overall impact on hospitals as a whole, and thus on small entities specifically, of the provisions of this final rule with comment period will not exceed the 3 to 5 percent threshold discussed previously. Therefore, the Secretary has determined that this final rule with comment period will not have significant economic impact on a substantial number of small entities. We note that for some hospitals, these estimates may represent the total expected impact on their inpatient hospital revenue; for other hospitals, this represents only a portion of the total expected impact, as much of their revenue comes from non-Medicare cases. We estimate that hospitals will experience a net benefit resulting from the GME provisions of this final rule with comment period, as such we do not expect small entities to incur significant costs.

This final rule with comment period contains a range of policies. It provides descriptions of the statutory provisions that are addressed, identifies the policies, and presents rationales for our decisions and, where relevant, alternatives that were considered, including those alternatives discussed in section IV.E. of this final rule with comment period. The analyses discussed in this RIA and throughout the preamble of this final rule with comment period constitutes our regulatory flexibility analysis. We solicited public comments on our estimates and analysis of the impact of our policies on small entities. We received no public comments on those estimates and analysis other than the comments noted in section IV.C.1. and IV.C.2. of this final rule with comment period. As discussed in section IV.C.2. of this final rule with comment period, there is no impact on hospitals or OPOs in FY 2022 from the final organ acquisition policies discussed in this final rule with comment period. Also, as discussed previously, in this final rule with comment period we are finalizing policies to implement section 126 of the CAA of 2021, which makes available 1,000 new Medicare-funded GME positions (but not more than 200 new positions for a fiscal year), to be distributed beginning in FY 2023. A separate round of applications from hospitals will be initiated for these

additional residency positions, and hospitals must be notified of the number of positions distributed to them by January 31 of the fiscal year, effective beginning July 1 of that fiscal year.

Teaching hospitals that apply timely and are awarded FTE residency positions will experience an increase in their Medicare GME payments once the hospital fills the positions. However, until hospitals submit applications requesting the FTE residency positions and submit documentation demonstrating they meet the eligibility criteria and other requirements, we do not know which hospitals or what types of hospitals will receive additional FTE residency positions under this provision. To the extent that small rural hospitals apply for and receive FTE residency positions under this provision, they will experience an increase in their GME payments. Therefore, the Secretary has certified that this final rule with comment period will have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. As explained previously, to the extent that small rural hospitals apply for and receive FTE residency positions, they will experience an increase in their GME payments. Therefore, the Secretary has certified that this final rule with comment period will have a significant impact on the operations of a substantial number of small rural hospitals.

However, we note that the organ acquisition policies for transplant hospitals will not have a significant impact, as no certified transplant hospitals are small rural hospitals. Additionally, while some donor community hospitals may be small rural hospitals, we are making changes to their billing practices which should not affect hospital operations as donor community hospitals will be paid the lesser of their reasonable cost or a negotiated rate.

We assume that the costs for reviewing this rule is the same for small entities as it is for larger entities. For each entity that reviews the rule, the estimated cost is $475.24 (4.16 hours × $114.24). Therefore, we estimate that the total cost of reviewing this rule is $270,886.80 ($475.24 × 570).

H. Unfunded Mandates Reform Act (UMRA)

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 in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately $158 million. This final rule with comment period would not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $158 million in any 1 year.

I. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule with comment period) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This rule will not have a substantial direct effect on state or local governments, preempt states, or otherwise have a Federalism implication.

This final rule with comment period is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on December 14, 2021.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, and Reporting and recordkeeping requirements.

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services is amending 42 CFR Chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for Part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 412.1 is amended by revising paragraph (a)(1)(ii) to read as follows:

§ 412.1 Scope of part.

(a) * * *

(1) * * *

(ii) Payment for other costs related to inpatient hospital services is made on a reasonable cost basis as follows:

(A) Organ acquisition costs incurred by hospitals with approved organ transplant programs.

(B) The costs of qualified nonphysician anesthetist's services, as described in § 412.113(c).

(C) Direct costs of approved nursing and allied health educational programs.

(D) Costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant as described in § 412.113(e).

* * * * *

■ 3. Section 412.2 is amended by revising paragraph (e)(4) to read as follows:

§ 412.2 Basis of payment.

* * * * *

(e) * * *

(4) The acquisition costs of hearts, kidneys, livers, lungs, pancreas, and intestines (or multivisceral organs) incurred by approved transplant programs.

* * * * *

■ 4. Section 412.71 is amended by revising paragraph (b)(3) to read as follows:

§ 412.71 Determination of base-year inpatient operating costs.

* * * * *

(b) * * *

(3) Kidney acquisition costs incurred by hospitals with approved kidney transplant programs as described in § 412.100. Kidney acquisition costs in the base year are determined by multiplying the hospital's average kidney acquisition cost per kidney times the number of kidney transplants

covered by Medicare Part A during the base period.

* * * * *

■ 5. Section 412.90 is amended by revising paragraph (d) to read as follows:

§ 412.90 General rules.

* * * * *

(d) *Kidney acquisition costs incurred by hospitals with approved kidney transplant programs.* CMS pays for kidney acquisition costs incurred by kidney transplant programs on a reasonable cost basis. The criteria for this special payment provision are set forth in § 412.100.

* * * * *

■ 6. Section 412.100 is revised to read as follows:

§ 412.100 Special treatment: Kidney transplant programs.

(a) *Adjustments for kidney transplant programs.* (1) CMS adjusts the inpatient prospective payment system (IPPS) rates for inpatient operating costs determined under subparts D and E of this part for hospitals with approved kidney transplant programs (discussed at § 482.104 of this chapter) to remove the net costs associated with kidney acquisition.

(2)(i) Payment for Medicare kidney acquisition costs, as set forth in subpart L of part 413 of this chapter, is made on a reasonable cost basis apart from the prospective payment rate for inpatient operating costs.

(ii) IPPS payment to the hospital is adjusted in each cost reporting period to reflect an amount necessary to compensate the hospital for reasonable costs of Medicare kidney acquisition.

(b) *Costs of kidney acquisition.* Kidney acquisition costs include costs incurred in the acquisition of a kidney from a living or a cadaveric donor, by the hospital or an organ procurement organization, as appropriate. These costs are listed in § 413.402(b) of this chapter.

■ 7. Section 412.105 is amended by:

■ a. Revising paragraph (a)(1)((i);

■ b. Adding paragraph (f)(1)(iv)(C)(*3*); and

■ c. Revising paragraphs (f)(1)(v)(F), (f)(1)(vii), and (f)(1)(x).

The addition and revisions read as follows:

§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

(a) * * *

(1) * * *

(i) Except for the special circumstances for Medicare GME affiliated groups, emergency Medicare GME affiliated groups, and new programs described in paragraphs (f)(1)(vi) and (f)(1)(vii) of this section for cost reporting periods beginning on or after October 1, 1997, and for the special circumstances for closed hospitals or closed programs described in paragraph (f)(1)(ix) of this section for cost reporting periods beginning on or after October 1, 2002, and for Rural Track Programs within their 5-year cap building period described in paragraph (f)(1)(x)(B) in cost reporting periods beginning on or after October 1, 2022, this ratio may not exceed the ratio for the hospital's most recent prior cost reporting period after accounting for the cap on the number of allopathic and osteopathic full-time equivalent residents as described in paragraph (f)(1)(iv) of this section, and adding to the capped numerator any dental and podiatric full-time equivalent residents.

* * * * *

(f) * * *

(1) * * *

(iv) * * *

(C) * * *

(*3*) Effective for portions of cost reporting periods beginning on or after July 1, 2023, a hospital may qualify to receive an increase in its otherwise applicable FTE resident cap if the criteria specified in § 413.79(p) of this subchapter are met.

* * * * *

(v) * * *

(F)(*1*) Subject to the provisions of paragraph (f)(1)(x) of this section, effective for cost reporting periods beginning on or after April 1, 2000, and beginning before October 1, 2022, full-time equivalent residents at an urban hospital in a rural track program are included in the urban hospital's rolling average calculation described in paragraph (f)(1)(v)(B) of this section.

(*2*) Subject to the provisions of paragraph (f)(1)(x) of this section, for cost reporting periods beginning on or after October 1, 2022, full-time equivalent residents at an urban hospital or rural hospital in a Rural Track Program are excluded from the rolling average calculation described in paragraph (f)(1)(v)(B) of this section during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each rural track.

* * * * *

(vii)(A) If a hospital establishes a new medical residency training program, as defined in § 413.79(l) of this subchapter, the hospital's full-time equivalent cap may be adjusted in accordance with the provisions of § 413.79(e) of this subchapter.

(B)(*1*) A hospital that, as of December 27, 2020, has a full-time equivalent cap of less than 1.0 FTE based on a cost reporting period beginning before October 1, 1997, that begins training residents in a new medical residency training program, as defined at § 413.79(l) of this subchapter, in a cost reporting period beginning on or after December 27, 2020, and before December 26, 2025, may receive an adjustment to its full-time equivalent cap when it trains at least 1.0 FTE in such new medical residency training program(s), to be calculated in accordance with § 413.79(e) of this subchapter.

(*2*) A hospital that has a full-time equivalent cap of no more than 3.0 FTEs based on a cost reporting period beginning on or after October 1, 1997, and before December 27, 2020, that begins training residents in a new medical residency training program, as defined at § 413.79(l) of this subchapter, in a cost reporting period beginning on or after December 27, 2020 and before December 26, 2025, may receive an adjustment to its full-time equivalent cap when it trains more than 3.0 FTE in such new medical residency training program(s), to be calculated in accordance with the provisions of § 413.79(e) of this subchapter.

* * * * *

(x)(A) For rural track programs started in a cost reporting period beginning before October 1, 2022, an urban hospital that establishes a new residency program (as defined in § 413.79(l) of this subchapter), or has an existing residency program, with a rural track (or an integrated rural track) may include in its FTE count residents in those rural tracks in accordance with the applicable provisions of § 413.79(k) of this subchapter.

(B) For cost reporting periods beginning on or after October 1, 2022, an urban hospital or rural hospital that establishes a new residency program (as defined in § 413.79(l) of this subchapter) that is a Rural Track Program (as defined at § 413.75(b) of this subchapter), or adds an additional site to a Rural Track Program, may include in its FTE count residents in the Rural Track Program in accordance with the applicable provisions of § 413.79(k) of this subchapter.

* * * * *

■ 8. Section 412.113 is amended by revising paragraph (d) to read as follows:

§ 412.113 Other payments.

* * * * *

(d) *Organ acquisition.* Payment for organ acquisition costs as specified in part 413, subpart L, incurred by hospitals with approved transplant programs is made on a reasonable cost basis.

* * * * *

■ 8. Section 412.116 is amended by revising paragraph (c) to read as follows:

§ 412.116 Method of payment.

* * * * *

(c) *Special interim payments for certain costs.* For capital-related costs for cost-reporting periods beginning before October 1, 1991, and the direct costs of medical education, which are not included in prospective payments but are reimbursed as specified in §§ 413.130 and 413.85 of this chapter, respectively, interim payments are made subject to final cost settlement. Interim payments for capital-related items for cost-reporting periods beginning before October 1, 1991, and the estimated cost of approved medical education programs (applicable to inpatient costs payable under Medicare Part A and for kidney acquisition costs in hospitals with approved kidney transplant programs) are determined by estimating the reimbursable amount for the year based on the previous year's experience and on substantiated information for the current year and divided into 26 equal biweekly payments. Each payment is made 2 weeks after the end of a biweekly period of services, as described in § 413.64(h)(5) of this subchapter. The interim payments are reviewed by the intermediary at least twice during the reporting period and adjusted if necessary.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 9. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 10. Section 413.1 is amended by revising paragraphs (a)(2)(v) and (d)(2)(i) to read as follows:

§ 413.1 Introduction.

(a) * * *

(2) * * *

(v) Organ procurement organizations (OPOs) and histocompatibility laboratories.

* * * * *

(d) * * *

(2) * * *

(i) Payment for the following is described in § 412.113 of this chapter:

(A) Capital related costs for cost reporting periods beginning before October 1991.

(B) Medical education costs.

(C) Organ acquisition costs as specified in part 413, subpart L.

(D) The costs of certain anesthesia services.

* * * * *

■ 11. Section 413.40 is amended by revising paragraph (a)(3) to read as follows:

§ 413.40 Ceiling on the rate of increase in hospital inpatient costs.

(a) * * *

(3) *Net inpatient operating costs* include the costs of certain preadmission services as specified in paragraph (c)(2) of this section, the costs of routine services, ancillary services, and intensive care services (as defined in § 413.53(b)) incurred by a hospital in furnishing covered inpatient services to Medicare beneficiaries. Net inpatient operating costs exclude capital-related costs as described in § 413.130, the costs of approved medical education programs as described in §§ 413.75 through 413.83 and 413.85, and organ acquisition costs as specified in subpart L of this part incurred by approved transplant programs. These costs are identified and excluded from inpatient operating costs before the application of the ceiling.

* * * * *

■ 12. In § 413.75 amend paragraph (b) by:

■ a. In the definition of ''Rural track FTE limitation'', by removing the phrase ''urban hospital may include in its'' and adding in its place the phrase ''urban hospital or rural hospital may include in its'';

■ b. Revising the definition of ''Rural track or integrated rural track''; and

■ c. Adding in alphabetical order the definition of ''Rural Track Program''.

The addition and revision read as follows:

§ 413.75 Direct GME payments: General requirements.

* * * * *

(b) * * *

Rural track or integrated rural track means, for programs started in cost reporting periods prior to October 1, 2022, an approved medical residency training program established by an urban hospital in which residents train for a portion of the program at the urban hospital and then rotate for a portion of the program to a rural hospital(s) or a rural nonhospital site(s).

Rural Track Program means, effective for cost reporting periods beginning on or after October 1, 2022, an ACGME-accredited program in which residents/fellows gain both urban and rural experience with more than half of the education and training for a resident/fellow taking place in a rural area as defined at 42 CFR 412.62(f)(iii).

* * * * *

■ 13. Section 413.77 is amended by revising paragraph (e)(1)(iii) and adding paragraphs (e)(1)(iv) and (v) to read as follows:

§ 413.77 Direct GME payments: Determination of per resident amounts.

* * * * *

(e) * * *

(1) * * *

(iii) If, under paragraph (e)(1)(ii)(A) or (B) or (e)(1)(iv)(B) of this section, there are fewer than three existing teaching hospitals with per resident amounts that can be used to calculate the weighted mean value per resident amount, for base periods beginning on or after October 1, 1997, the per resident amount equals the updated weighted mean value of per resident amounts of all hospitals located in the same census region as that term is used in subpart D of part 412 of this subchapter.

(iv) A hospital that, as of December 27, 2020, has a per resident amount based on less than 1.0 FTE in any cost reporting period beginning before October 1, 1997, may choose to receive a recalculated per resident amount either when it trains at least 1.0 FTE in the earliest cost reporting period beginning on or after December 27, 2020, and before December 26, 2025, or when it trains at least 1.0 FTE in the first cost reporting period beginning after December 27, 2021. A hospital that, as of December 27, 2020, has a per resident amount based on no more than 3.0 FTEs in any cost reporting period beginning on or after October 1, 1997, and before December 27, 2020, may choose to receive a recalculated per resident amount either when it trains more than 3.0 FTEs in the earliest cost reporting period beginning on or after December 27, 2020 and before December 26, 2025, or when it trains more than 3.0 FTE in the first cost reporting period beginning after December 27, 2021. In either case, residents need not be on duty during the first month of the cost reporting period. The recalculated per

resident amount is based on the lower of—

(A) The hospital's actual cost per resident incurred in connection with the GME program(s) based on the cost and resident data from the hospital's base year cost reporting period, which is, for hospitals with a per resident amount previously based on less than 1.0 FTE, either when it trains at least 1.0 FTE in the earliest cost reporting period beginning on or after December 27, 2020, and before December 26, 2025, or when it trains at least 1.0 FTE in the first cost reporting period beginning after December 27, 2021; and for hospitals with a per resident amount previously based on not more than 3.0 FTEs, either when it trains more than 3.0 FTEs in the earliest cost reporting period beginning on or after December 27, 2020 and before December 26, 2025, or when it trains more than 3.0 FTE in the first cost reporting period beginning after <SECTION><SECTNO>; or

(B) The updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area is calculated using all per resident amounts (including primary care and obstetrics and gynecology and nonprimary care) and FTE resident counts from the most recently settled cost reports of those teaching hospitals.

(v) Effective for a cost reporting periods beginning on or after December 27, 2020, a per resident amount must be established if a hospital trains less than 1.0 FTE resident and this training results from the hospital's participation in a Medicare GME affiliation agreement under § 413.79(f). Effective for a cost reporting period beginning on or after December 27, 2020, a per resident amount must only be established when the hospital trains at least 1.0 FTE and does not participate in a Medicare GME affiliation agreement under § 413.79(f) for that training. Residents need not be on duty during the first month of the cost reporting period from which the per resident amount is established.

* * * * *

■ 14. Section 413.78 is amended by revising paragraph (b) to reads as follows:

§ 413.78 Direct GME payments: Determination of the total number of FTE residents.

* * * * *

(b)(1) No individual resident may be counted as more than one FTE based on the total time spent in training at all sites. A hospital cannot claim the time spent by residents training at another hospital, except as provided in paragraph (i) of this section. Except as provided in paragraphs (c), (d), and (e) of this section, if a resident spends time in more than one hospital or in a non-provider setting, the resident counts as partial FTE based on the proportion of time worked at the hospital to the total time worked. A part-time resident counts as a partial FTE based on the proportion of allowable time worked compared to the total time necessary to fill a full-time internship or residency slot.

(2) Effective for a cost reporting period beginning on or after December 27, 2020, a hospital must report FTE residents on its Medicare cost report for a cost reporting period if it does not participate in a Medicare GME affiliation agreement (as defined under § 413.75(b)), and the hospital trains at least 1.0 FTE in an approved program or programs, or, if the hospital trains less than 1.0 FTE residents in an approved program or programs and this training results from the hospital's participation in a Medicare GME affiliation agreement (as defined under § 413.75(b)).

* * * * *

■ 15. Section 413.79 is amended by—
■ a. Revising paragraph (c)(2) introductory text;
■ b. Revising paragraph (d)(7);
■ c. Adding paragraphs (e)(1)(vi), (e)(6), and (f)(8);
■ d. Revising paragraphs (k) introductory text, (k)(1), (k)(2) introductory text, (k)(2)(i), and (k)(3);
■ e. Adding paragraph (k)(4)(i)(C);
■ f. Revising paragraph (k)(4)(ii) introductory text;
■ g. Adding (k)(4)(ii)(C);
■ h. In paragraph (k)(5)(i), removing the phrase ''An urban hospital may not include in its rural track FTE limitation or (assuming the urban hospital's FTE'' and adding in its place the phrase ''A hospital may not include in its rural track FTE limitation or (assuming the hospital's FTE'';
■ i. In paragraph (k)(5)(ii), removing the phrase ''The hospital'' and adding in its place the phrase ''Each hospital''; and
■ j. Adding paragraphs (k)(5)(iv) and (p).

The revisions and additions read as follows:

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

* * * * *

(c) * * *

(2) *Determination of the FTE resident cap.* Subject to the provisions of paragraphs (c)(3) through (6) and (m) through (p) of this section and § 413.81, for purposes of determining direct GME payment—

* * * * *

(d) * * *

(7)(i) Subject to the provisions under paragraph (k) of this section, effective for cost reporting periods beginning on or after April 1, 2000 and before cost reporting periods beginning on or after October 1, 2022, FTE residents in a rural track program at an urban hospital are included in the urban hospital's rolling average calculation described in this paragraph (d).

(ii) Subject to the provisions under paragraph (k) of this section, effective for rural track programs started in a cost reporting period beginning on or after October 1, 2022, FTE residents in a rural track program at an urban hospital or rural hospital are excluded from rolling average calculation described in this paragraph (d) during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each rural track.

(e) * * *

(1) * * *

(vi) In the case of a hospital that, as of December 27, 2020, has a FTE cap based on the training of less than 1.0 FTE in any cost reporting period beginning before October 1, 1997; or based on the training of no more than 3.0 FTEs in on a cost reporting period beginning on or after October 1, 1997, and before December 27, 2020, if such a hospital begins training residents in a new approved program (as defined under § 413.79(l)) in a program year beginning on or after December 27, 2020 and before December 26, 2025, the hospital with a previous FTE cap of less than 1.0 FTE may receive an adjusted FTE cap when it begins to train at least 1.0 FTE in a new program(s); and the hospital with a previous FTE cap of no more than 3.0 FTEs may receive an adjusted FTE cap when it begins to train more than 3.0 FTEs in a new program(s). The adjusted FTE cap is equal to the sum of the original FTE cap and the products of the following three factors (limited to the number of accredited slots for each program):

(A) The highest total number of FTE residents trained in any program year during the fifth year of the first new program's existence started in a program year beginning on or after December 27, 2020 and before December 26, 2025, at all of the hospitals to which the residents in the program rotate;

(B) The number of years in which residents are expected to complete the program, based on the minimum accredited length for each type of program.

(C) The ratio of the number of FTE residents in the new program that trained at the hospital over the entire 5-

year period to the total number of FTE residents that trained at all hospitals over the entire 5-year period.

* * * * *

(6) Effective for a cost reporting period beginning on or after December 27, 2020, FTE resident caps must be established when the hospital trains 1.0 or more FTE residents in a new medical residency program (as defined under paragraph (l) of this section).

(f) * * *

(8) FTE resident cap slots added under section 126 of Public Law 116–260 may be used in a Medicare GME affiliation agreement beginning in the fifth year after the effective date of those FTE resident cap slots.

* * * * *

(k) *Residents training in rural track programs.* Subject to the provisions of § 413.81, an urban hospital that establishes a new residency program, or has an existing residency program, with a rural track (or an integrated rural track) may add the rotations of the residents in those rural tracks to its FTE cap specified under paragraph (c) of this section. An urban hospital (or, effective for a cost reporting period beginning on or after October 1, 2022, a rural hospital) with a Rural Track Program (as defined at section 413.75(b) of this subchapter) may count residents in those Rural Track Programs up to a rural track FTE limitation if the hospital complies with the conditions specified in paragraphs (k)(2) through (7) of this section.

(1) If an urban hospital rotates residents to a separately accredited rural track program at a rural hospital(s) for two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, and before October 1, 2022, the urban hospital may include those residents in its FTE count for the time the rural track residents spend at the urban hospital, not to exceed its rural track FTE limitation. For cost reporting periods beginning on or after October 1, 2022, if an urban hospital rotates residents to a Rural Track Program (as defined at section 413.75(b) of this subchapter) at a rural hospital(s) for more than one-half of the duration of the program, both the urban and the rural hospital may include those residents in their FTE counts for the time the rural track residents spend at the urban and rural hospital, respectively, not to exceed their rural track FTE limitations. The rural track FTE limitation is determined as follows:

(i) For rural track programs started prior to October 1, 2012, for the first 3 years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average at paragraph (d)(7) of this section, training in the rural track at the urban hospital. For rural track programs started on or after October 1, 2012, and before October 1, 2022, prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average at paragraph (d)(7) of this section, training in the rural track at the urban hospital. For cost reporting periods beginning on or after October 1, 2022, before the start of the urban or rural hospital's cost reporting period that coincides with or follows the start of the sixth program year of the Rural Track Program's existence, the rural track FTE limitation for each hospital will be the actual number of FTE residents training in the Rural Track Program at the urban or rural hospital.

(ii) For rural track programs started prior to October 1, 2012, beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of the highest number of residents, in any program year, who during the third year of the rural track's existence are training in the rural track at the urban hospital and are designated at the beginning of their training to be rotated to the rural hospital(s) for at least two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, and the number of years those residents are training at the urban hospital. For rural track programs started on or after October 1, 2012 and before October 1, 2022, beginning with the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is calculated in accordance with paragraph (e)(1) of this section. For Rural Track Programs started on or after October 1, 2022, beginning with the start of the urban or rural hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is calculated in accordance with paragraph (e)(1) of this section.

(2) If an urban hospital rotates residents to a separately accredited rural track program at a rural nonprovider site(s) for two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(d) through (g). For cost reporting periods beginning on or after October 1, 2022, if an urban or rural hospital rotates residents to a Rural Track Program (as defined at section 413.75(b) of this subchapter) at a rural nonprovider site for more than one-half of the duration of the program, the urban or rural hospital may include those residents in its FTE count, subject to which hospital meets the requirements under § 413.78(g), not to exceed their rural track FTE limitations. The rural track FTE limitation is determined as follows:

(i) For rural track programs started prior to October 1, 2012, for the first 3 years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonprovider site(s). For rural track programs started on or after October 1, 2012, and before October 1, 2022, prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonprovider site(s). For Rural Track Programs prior to the start of the urban or rural hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each respective hospital will be the actual number of FTE residents training in the Rural Track Program at the hospital and, subject to the requirements under § 413.78(g), in the rural nonprovider site(s).

* * * * *

(3) For rural track programs started prior to October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural hospital(s) for

less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the rural hospital may not include those residents in its FTE count (unless the rural track is a new program under paragraph (e)(3) of this section, or the rural hospital's FTE count does not exceed that hospital's FTE cap), nor may the urban hospital include those residents when calculating its rural track FTE limitation. For rural track programs started on or after October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural hospital(s) for one-half or less than one-half of the duration of the program, the rural hospital may not include those residents in its FTE count (unless the rural track is a new program under paragraph (e)(3) of this section, or the rural hospital's FTE count does not exceed that hospital's FTE cap), nor may the urban hospital include those residents when calculating its rural track FTE limitation. For cost reporting periods beginning on or after October 1, 2022, if less than or equal to 50 percent of the duration of the training program occurs in a rural area, neither the urban or rural hospital may receive a rural track FTE limitation.

(4) * * *

(i) * * *

(C) For programs started in a cost reporting period beginning on or after October 1, 2022, if less than or equal to 50 percent of the duration of the training program occurs in a rural area, neither the urban or rural hospital may receive a rural track FTE limitation.

(ii) For rural track programs started on or after October 1, 2012 and prior to October 1, 2022, if an urban hospital rotates residents in the rural track program to a rural nonprovider site(s) for one-half or less than one-half of the duration of the program, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(g). The urban hospital may include in its FTE count those residents in the rural track, not to exceed its rural track limitation, determined as follows:

* * * * *

(C) For cost reporting periods beginning on or after October 1, 2022, if less than or equal to 50 percent of the duration of the training program occurs in a rural area, neither the urban or rural hospital may receive a rural track FTE limitation.

(5) * * *

(iv) Effective for cost reporting periods beginning on or after October 1, 2022, in order for an urban or rural hospital to receive a rural track FTE limitation, greater than 50 percent of the program must occur in a rural area.

* * * * *

(p) *Determination of an increase in the otherwise applicable resident cap under section 126 of the Consolidated Appropriations Act (Pub. L. 116–260).* For portions of cost reporting periods beginning on or after July 1, 2023, a hospital may receive an increase in its otherwise applicable FTE resident cap (as determined by CMS) if the hospital meets the requirements and qualifying criteria under section 1886(h)(9) of the Act and if the hospital submits an application to CMS within the timeframe specified by CMS.

Subpart H—Payment for End-Stage Renal Disease (ESRD) Services

■ 16. The subpart heading for Subpart H is revised to read as set forth above.

§§ 413.200 [Removed and Reserved]

■ 17. Section 413.200 is removed and reserved.

■ 18. Subpart L is added to read as follows:

Subpart L—Payment of Organ Acquisition Costs for Transplant Hospitals, Organ Procurement Organizations, and Histocompatibility Laboratories

Sec.

Subpart L—Payment of Organ Acquisition Costs for Transplant Hospitals. Organ Procurement Organizations, and Histocompatibility Laboratories

§ 413.400 Definitions.

As used in this subpart:

Histocompatibility laboratory means a laboratory meeting the requirements set forth in § 493.1227 of this chapter and providing the services for the acquisition of kidneys or other organs for transplantation.

Hospital-based organ procurement organization (HOPO) means an organ procurement organization that is considered a department of the transplant hospital and reports organ acquisition costs it incurs on the transplant hospital's Medicare cost report.

Independent organ procurement organization (IOPO) means an organ procurement organization that files a Medicare cost report separate from a hospital and meets all of the following:

(1) Is not subject to the control of a hospital with respect to the hiring, firing, training, and paying of employees.

(2) Is not considered as a department of a hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance).

(3) Reports organ acquisition costs it incurs on the IOPO Medicare cost report.

Organ, for Medicare organ acquisition payment purposes, means:

(1) A human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine).

(2) Pancreata procured on or after October 1, 2004, for the purpose of acquiring pancreatic islet cells for transplantation into individuals who are participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial in accordance with section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

Organ procurement organization (OPO) means an organization defined in § 486.302 of this chapter. OPOs can be independent or hospital based.

Standard acquisition charge (SAC) means a charge as defined in § 413.404 of this chapter.

Transplant hospital means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

Transplant hospital/HOPO (TH/HOPO) refers to a transplant hospital, or a transplant hospital that operates a HOPO (as previously defined in this section) and performs organ procurement activities as one entity reported on the transplant hospital's Medicare cost report.

Transplant program means an organ-specific transplant program within a transplant hospital (as defined in this section).

§ 413.402 Organ acquisition costs.

(a) *Costs related to organ acquisition.* Costs recognized in paragraph (b) of this section are costs incurred in the acquisition of organs from a living donor or a cadaveric donor, by the hospital or an organ procurement organization, as appropriate. Additionally, there are administrative and general costs that may be allowable and included on the cost report for an OPO or TH/HOPO.

(b) *Types of costs.* Organ acquisition costs are as follows:

(1) Tissue typing, including tissue typing furnished by independent laboratories.

(2) Donor and beneficiary evaluation.

(3) Other costs associated with excising organs, such as general routine and special care services (for example, intensive care unit or critical care unit services), provided to the living or cadaveric donor.

(4) Operating room and other inpatient ancillary services applicable to the living or cadaveric donor.

(5) Organ preservation and perfusion costs.

(6) Organ Procurement and Transplantation Network registration fees, and the reasonable and necessary cost of other fees, such as the registration fees for a kidney paired exchange, to register candidates for organ transplants. These allowable registry fees must support or promote organ transplantation and must not be duplicative in nature.

(7) Surgeons' fees for excising cadaveric organs (currently limited to $1,250 for kidneys).

(8) Transportation of the:

(i) Excised organ to the transplant hospital; and

(ii) Cadaveric donor to procure organs when it is necessary to preserve clinical outcomes or to avoid loss of potentially transplantable organs.

(9) Costs of organs acquired from other hospitals or organ procurement organizations.

(10) Hospital costs normally classified as outpatient costs applicable to organ excisions (services include donor and recipient tissue typing, work-up, and related services furnished prior to inpatient admission).

(11) Costs of services applicable to organ excisions which are rendered by residents and interns not in approved teaching programs.

(12) All pre-admission services applicable to organ excisions, such as laboratory, electroencephalography, and the costs of physicians' services.

(c) *Living donor complications.* (1) *Living kidney donor complications.* Living kidney donor complications directly related to the kidney donation, which occur after the date of the donor's discharge, must not be reported as kidney acquisition costs on the Medicare cost report.

(A) Medicare covers reasonable costs incurred for living kidney donor complications only if they are directly related to a kidney donation for a covered transplant into a Medicare beneficiary.

(B) Living kidney donor complications are paid through the claims processing system under Medicare Part A or Part B, as applicable for the services provided, with no donor liability for deductibles or coinsurance. Living kidney donor complications are billed under the Medicare Beneficiary Identifier of the transplant recipient.

(2) *Living non-renal donor complications.* Hospital costs incurred for living non-renal donor complications directly related to the non-renal organ donation, which occur after the date of the donor's discharge are not paid through the claims processing system but are reported as organ acquisition costs on the hospital's Medicare cost report.

(A) Medicare covers reasonable hospital costs incurred for living non-renal organ donor complications only if they are directly related to a non-renal organ donation for a covered transplant into a Medicare beneficiary.

(B) Hospital costs incurred for living non-renal organ donor complications are reported as organ acquisition costs on the Medicare cost report, and paid through the cost report on a reasonable cost basis.

(d) *Costs not related to organ acquisition.* (1) Items or services that are not related or reasonable to acquire an organ for transplantation, non-allowable administrative and general costs, or costs that are not related to patient care, are not considered organ acquisition costs.

(2) Examples of items or services that are not organ acquisition costs include, but are not limited to the following:

(i) Donor burial and funeral expenses.

(ii) Transportation costs of the cadaveric donor after organ procurement for funeral services or for burial.

(iii) Transportation costs for a living donor.

(iv) Fees or in-center payments for donor referrals.

(v) Costs associated with and incurred for OPO-sponsored seminars where continuing education credits are given and where the attendee is not on the OPO's staff (as described at § 486.326(b)).

(vi) Unreasonable costs incurred for administrator's duties associated with professional organizations.

§ 413.404 Standard acquisition charge.

(a) *General.* (1) Procuring an organ is not a covered service when performed independent of a Medicare covered transplant, however, the reasonable costs to procure an organ are reimbursable when billed in connection with a Medicare covered transplant.

(2) The SAC represents the average of the total organ acquisition costs associated with procuring either cadaveric donor organs or living donor organs, by organ type.

(3) When a TH/HOPO or IOPO furnishes an organ to another TH/HOPO or IOPO, it bills its SAC to the TH/HOPO or IOPO receiving the organ.

(b) *THs/HOPOs SACs.* (1) A TH/HOPO must develop a SAC for each organ type (for example heart, liver, or lung).

(2) When a TH/HOPO furnishes an organ to another transplant hospital or IOPO, it must bill the receiving transplant hospital or IOPO its SAC by organ type, or the hospital's standard departmental charges that are reduced to cost.

(3) A transplant hospital must establish SACs for living donor organs. A TH/HOPO must establish SACs for cadaveric donor organs.

(i) *Living donor SAC for transplant hospitals*—(A) *Definition.* The living donor SAC is an average organ acquisition cost that a transplant hospital incurs to procure an organ from a living donor.

(B) *Establishment of living donor SAC.* A transplant hospital must establish a living donor SAC (living SAC) before the transplant hospital bills its first living donor transplant to Medicare.

(C) *Calculating the living donor SAC*—(*1*) *Initial living donor SAC.* A transplant hospital calculates its initial living donor SAC for each living organ type as follows:

(*i*) By estimating the reasonable and necessary organ acquisition costs it expects to incur for services furnished to living donors, and pre-admission

services furnished to recipients of living donor organs during the hospital's cost reporting period.

(*ii*) By dividing the estimated amount described in paragraph (b)(3)(i)(C)(*1*)(*i*) of this section by the projected number of usable living donor organs to be procured by the transplant hospital during the transplant hospital's cost reporting period.

(*2*) *Subsequent living donor SAC.* A transplant hospital calculates its subsequent years' living donor SAC for each living organ type as follows:

(*i*) By using the transplant hospital's actual organ acquisition costs for the living donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year.

(*ii*) Dividing the costs in paragraph (b)(3)(i)(C)(*2*)(*i*) of this section by the actual number of usable living donor organs procured by the transplant hospital during that prior cost reporting period.

(D) *Costs used to develop the living donor SAC.* Costs that may be used to develop the living donor SAC include, but are not limited to the following:

(*1*) Costs of tissue typing services, including those furnished by independent laboratories.

(*2*) Costs of physician pre-admission transplant evaluation services.

(*3*) Registry fees as specified at § 413.402(b)(6) of this subpart.

(*4*) Costs for donor and recipient evaluations and workups furnished prior to admission for transplantation.

(*5*) Other costs associated with procurement, for example, general routine and special care services (for example, intensive care unit or critical care unit services), related to the donor.

(*6*) Costs of operating room and other inpatient ancillary services related to the donor.

(*7*) Organ preservation and perfusion costs.

(*8*) Transportation costs of the excised organ as specified in § 413.402(b)(8)(i) of this subpart.

(ii) *Cadaveric donor SAC for THs/HOPOs*—(A) *Definition.* The cadaveric donor SAC is an average cost that a TH/HOPO incurs to procure a cadaveric donor organ.

(B) *Calculating the cadaveric SAC*—(*1*) *Initial cadaveric donor SAC.* A TH/HOPO calculates its initial cadaveric SAC for each cadaveric organ type as follows:

(*i*) By estimating the reasonable and necessary costs it expects to incur to procure cadaveric organs, combined with the expected costs of acquiring cadaveric organs from OPOs or other transplant hospitals.

(*ii*) By dividing the estimated amount described in paragraph (b)(3)(ii)(B)(*1*)(*i*) of this section by the projected number of usable cadaveric organs to be procured by the TH/HOPO within the transplant hospital's cost reporting period.

(*2*) *Subsequent cadaveric donor SAC.* A TH/HOPO calculates its subsequent years' cadaveric donor SAC for each cadaveric organ type as follows:

(*i*) By using the transplant hospital's actual organ acquisition costs for the cadaveric donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year.

(*ii*) By dividing the costs in paragraph (b)(3)(ii)(B)(*2*)(*i*) of this section by the actual number of usable cadaveric donor organs procured by the TH/HOPO during that prior cost reporting period.

(C) *Costs to develop the cadaveric donor SAC.* Costs that may be used to develop the cadaveric donor SAC include, but are not limited to the following:

(*1*) Costs of organs acquired from other transplant hospitals or OPOs.

(*2*) Costs of transportation as specified in § 413.402(b)(8) of this subpart.

(*3*) Surgeons' fees for excising cadaveric organs (currently limited to $1,250 for kidneys).

(*4*) Costs of tissue typing services, including those furnished by independent laboratories.

(*5*) Organ preservation and perfusion costs.

(*6*) General routine and special care service costs (for example, intensive care unit or critical care unit services related to the donor).

(*7*) Operating room and other inpatient ancillary service costs.

(c) *Independent OPO SACs*—(1) *Non-renal SAC.* An IOPO establishes non-renal SACs based on its costs of procuring non-renal organs for each organ type, by—

(i) Estimating the reasonable and necessary costs it expects to incur for services furnished to procure cadaveric donor non-renal organs during the IOPO's cost reporting period; and

(ii) Dividing the amount estimated in paragraph (c)(1)(i) of this section by the projected number of cadaveric donor non-renal organs the IOPO expects to procure within its cost reporting period.

(iii) An IOPO may adjust its non-renal SACs during the year if necessary to account for cost changes.

(2) *Kidney SAC.* (i) *General.* An IOPO's Medicare contractor establishes the kidney SAC based on an estimate of, initial year projected or subsequent years' actual, reasonable and necessary costs the IOPO expects to incur to procure cadaveric kidneys during the IOPO's cost reporting period, divided by the, initial year projected or subsequent years' actual, number of usable cadaveric kidneys the IOPO expects to procure.

(ii) *Initial year.* The Medicare contractor develops the IOPO's initial kidney SAC based on the IOPO's budget information.

(iii) *Subsequent years.* The kidney SAC for subsequent years is computed using the IOPO's costs related to kidney acquisition that were incurred in the prior cost reporting period and dividing those costs by the number of usable cadaveric kidneys procured during that cost reporting period. The SAC is the basis for the interim payments by the transplant hospital to the IOPO, as set forth in § 413.420(d).

(iv) The IOPO's Medicare contractor may adjust the kidney SAC during the year, if necessary, for cost changes.

(v) The IOPO cannot use or change its kidney SAC without the contractor's approval.

(3) *Billing SACs for organs generally.* When an IOPO obtains an organ from another IOPO, the receiving IOPO is responsible for paying the procuring IOPO's SAC. The receiving IOPO uses its SAC for each organ type and not the procuring IOPO's SAC when billing the transplant hospital receiving the organ.

§ 413.406 Acquisition of pancreata for islet cell transplant.

(a) Medicare only covers and pays for reasonable costs of acquisition on or after October 1, 2004, of pancreata for islet cell transplants into Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial of islet cell transplantation in accordance with section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

(b) Pancreata procured under paragraph (a), for covered islet cell transplants must be assigned a full standard acquisition charge and be treated as solid organs for procurement purposes.

§ 413.408 [Reserved]

§ 413.410 [Reserved]

§ 413.412 Intent to transplant, and counting en bloc, research, and discarded organs and kidneys.

(a) *Principle of intent to transplant for organ acquisition payment purposes.* (1) An organ is intended for transplant when the OPO or TH designates it for transplant prior to the time the donor enters the hospital's operating room for surgical excision/recovery of the organ(s).

(2) OPOs and THs must identify the costs associated with the recovered and

unrecovered organs and apportion those costs to the appropriate cost centers by organ type.

(b) *Counting en bloc organs.* En bloc organs can be en bloc lungs or en bloc kidneys. For Medicare cost allocation purposes, OPOs and THs count—

(1) En bloc lungs or en bloc kidneys procured and transplanted en bloc (two organs transplanted as one unit) as one total usable organ. En bloc organs transplanted into a Medicare beneficiary count as one Medicare usable organ or one Medicare usable kidney.

(2) En bloc lungs and en bloc kidneys procured en bloc but separated and transplanted into two different recipients as two total usable organs. For each organ transplanted into a Medicare beneficiary, count each as one Medicare usable organ or one Medicare usable kidney.

(c) *Research organs.* For Medicare cost allocation purposes, organs used for research are not counted as Medicare usable organs in Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)) and kidneys used for research are not counted as Medicare usable kidneys in Medicare's share of kidney acquisition costs.

(d) *Counting of discarded/unusable organs.* An organ is not counted as a Medicare usable organ or a total usable organ if the excising surgeon determines, upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and the organ is determined to be unusable and discarded.

§ 413.414 Medicare secondary payer and organ acquisition costs.

(a) *General principle.* If a Medicare beneficiary has a primary health insurer other than Medicare and that primary health insurer has primary liability for the transplant and organ acquisition costs, the Medicare Program may share a liability for organ acquisition costs as a secondary payer to the transplant hospital that performs the transplant in certain instances. To determine whether Medicare has liability to the transplant hospital that performs the transplant as a secondary payer for organ acquisition costs, it is necessary for the transplant hospital that performs the transplant to review the transplant hospital's agreement with the primary insurer.

(b) *Medicare has no secondary payer liability for organ acquisition costs.* If the primary insurer's agreement requires the transplant hospital to accept the primary insurer's payment as payment in full for the transplant and the associated organ acquisition costs, Medicare has zero liability as a secondary payer with no payment obligation for the transplantation costs or the organ acquisition costs, and the organ at issue is not a Medicare usable organ.

(c) *Medicare may have secondary payer liability for organ acquisition costs.* When the primary insurer's agreement does not require the transplant hospital that performs the transplant to accept the payment from the primary insurer as payment in full, and the payment the transplant hospital receives from the primary insurer for the transplant and organ acquisition costs is insufficient to cover the entire cost, Medicare may have a secondary payer liability to the transplant hospital that performs the transplant for the organ acquisition costs.

(1) To determine whether Medicare has a secondary payer liability for the organ acquisition costs, it is necessary for the transplant hospital that performs the transplant to submit a bill to its Medicare contractor and to compare the total cost of the transplant, including the transplant DRG amount and the organ acquisition costs, to the payment received from the primary payer.

(2) If the payment from the primary payer is greater than the cost of the transplant DRG and the organ acquisition costs, there is no Medicare liability and the transplant hospital must not count the organ as a Medicare usable organ.

(3) If the payment from the primary payer is less than the transplant DRG and the organ acquisition costs, there is a Medicare secondary payer liability and all of the following must occur:

(i) The transplant hospital must prorate the payment from the primary payer between the transplant DRG payment and the organ acquisition payment.

(ii) Only the transplant hospital that performs the transplant counts the organ as a Medicare usable organ.

(iii) The portion of the payment applicable to organ acquisition is used on the cost report to reduce the Medicare organ acquisition costs.

§ 413.416 Organ acquisition charges for kidney-paired exchanges.

(a) *Initial living donor evaluations.* When a recipient and donor elect to participate in a kidney paired exchange, the costs of the initial living donor evaluations are incurred by the originally intended recipient's transplant hospital, regardless of whether the living donor actually donates to their originally intended recipient, a kidney paired exchange recipient, or does not donate at all.

(b) *Additional tests after a match.* In a kidney paired exchange, regardless of whether an actual donation occurs, once the donor and recipient are matched, any additional tests requested by the recipient's transplant hospital and performed by the donor's transplant hospital, are billed to the recipient's transplant hospital as charges reduced to cost (using the donor's transplant hospital's cost to charge ratio) and included as acquisition costs on the recipient transplant hospital's Medicare cost report.

(c) *Procurement and transport of a kidney.* When a donor's transplant hospital procures and furnishes a kidney to a recipient's transplant hospital all of the following are applicable:

(1) All costs must be reasonable and necessary.

(2)(i) The donor's transplant hospital bills the recipient's transplant hospital.

(ii) The donor's transplant hospital bills its charges reduced to cost, or bills its applicable kidney SAC for the reasonable costs associated with procuring, packaging, and transporting the kidney.

(3) The donor's transplant hospital records the costs described in paragraph (c)(2)(ii) of this section on its Medicare cost report as kidney acquisition costs and offsets any payments received from the recipient's transplant hospital against its kidney acquisition costs.

(4) The recipient's transplant hospital records as part of its kidney acquisition costs—

(i) The amounts billed by the donor's transplant hospital for the reasonable costs associated with procuring, packaging, and transporting the organ; and

(ii) Any additional testing performed and billed by the donor's transplant hospital.

(d) *Donor's procurement occurs at recipient transplant hospital.* In a kidney-paired exchange—

(1) When a donor's transplant hospital does not procure a kidney, but the donor travels to the recipient's transplant hospital for the organ procurement, the reasonable costs associated with the organ procurement are included on the Medicare cost report of the recipient's transplant hospital; and

(2) The travel expenses of the living donor are not allowable Medicare costs.

§ 413.418 Amounts billed to organ procurement organizations by donor community hospitals and transplant hospitals for hospital services provided to cadaveric donors in the hospital and included as organ acquisition costs.

(a) *General.* A donor community hospital (a Medicare-certified non-transplant hospital) and a transplant hospital incur organ acquisition costs for donor organ procurement services, authorized by the OPO following declaration of death and consent to donate.

(b) *Amounts billed for organ acquisition costs.* For cost reporting periods beginning on or after February 25, 2022, when a donor community hospital or a transplant hospital incurs costs for services furnished to a cadaveric donor, as authorized by the OPO, the donor community hospital or transplant hospital must bill the OPO the lesser of its customary charges that are reduced to cost by applying its most recently available hospital specific cost-to-charge ratio for the period in which the service was rendered, or a negotiated rate.

§ 413.420 Payment to independent organ procurement organizations and histocompatibility laboratories for kidney acquisition costs.

(a) *Principle.* (1) Covered services furnished after September 30, 1978, by OPOs and histocompatibility laboratories in connection with kidney acquisition and transplantation are reimbursed under the principles for determining reasonable cost contained in this part.

(2) Services furnished by IOPOs and histocompatibility laboratories, that have an agreement with the Secretary in accordance with paragraph (c) of this section, are paid directly by the transplant hospital using a kidney SAC (for an IOPO) or contractor-established rates (for a histocompatibility laboratory). (The reasonable costs of services furnished by HOPOs or laboratories are reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.)

(b) *Definitions.* Definitions relevant to this section can be found in § 413.400.

(c) *Agreements with IOPOs and laboratories.* (1) Any IOPO or histocompatibility laboratory that wishes to have the cost of its pre-transplant services reimbursed under the Medicare program must file an agreement with CMS under which the IOPO or laboratory agrees to do all of the following:

(i) To file a cost report in accordance with § 413.24(f) within 5 months following the close of the period covered by the report.

(ii) To permit CMS to designate a contractor to determine the interim reimbursement rate payable by the transplant hospitals for services provided by the IOPO or laboratory and to determine the reasonable cost based upon the cost report filed by the IOPO or laboratory.

(iii) To provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate.

(iv) To pay to CMS amounts that have been paid by CMS to transplant hospitals and that are determined to be in excess of the reasonable cost of the services provided by the IOPO or laboratory.

(v) Not to charge any individual for items or services for which that individual is entitled to have payment made under section 1861 of the Act.

(2) The initial cost report due from an IOPO or laboratory is for its first fiscal year during any portion of which it had an agreement with the Secretary under paragraphs (c)(1) and (2) of this section. The initial cost report covers only the period covered by the agreement.

(d) *Interim reimbursement.* (1) Transplant hospitals with approved kidney transplant programs pay the IOPO or histocompatibility laboratory for their pre-transplantation services on the basis of an interim rate established by the contractor for that IOPO or laboratory.

(2) The interim rate is based on a kidney SAC or contractor established rates, associated with procuring a kidney for transplantation, incurred by an IOPO or laboratory respectively, during its previous fiscal year. If there is not adequate cost data to determine the initial interim rate, the Medicare contractor determines it according to the IOPO's or laboratory's estimate of its projected costs for the fiscal year.

(3) Payments made by transplant hospitals on the basis of interim rates are reconciled directly with the IOPO or laboratory after the close of its fiscal year, in accordance with paragraph (e) of this section.

(4) Information on the interim rate for all IOPOs and histocompatibility laboratories must be disseminated to all transplant hospitals and contractors.

(e) *Retroactive adjustment*—(1) *Cost reports.* Information provided in cost reports by IOPOs and histocompatibility laboratories must meet the requirements for cost data and cost finding specified in § 413.24. These cost reports must provide the following:

(i) A complete accounting of the cost incurred by the IOPO or laboratory in providing covered services, the total number of Medicare beneficiaries who received those services.

(ii) Any other data necessary to enable the contractor to determine the reasonable cost of covered services provided to Medicare beneficiaries.

(2) *Audit and adjustment.* A cost report submitted by an IOPO or histocompatibility laboratory is reviewed by the contractor and a new interim reimbursement rate for kidney acquisition costs for the subsequent fiscal year is established based upon this review.

(i) A retroactive adjustment in the amount paid under the interim rate is made in accordance with § 413.64(f).

(ii) If the determination of reasonable cost reveals an overpayment or underpayment resulting from the interim reimbursement rate paid to transplant hospitals, a lump sum adjustment is made directly between that contractor and the IOPO or laboratory.

(f) *Payment requirements.* For services furnished on or after April 1, 1988, no payment may be made for services furnished by an IOPO that does not meet the requirements of part 486, subpart G, of this chapter.

(g) *Appeals.* If the amount in controversy is $1,000 or more, any IOPO or histocompatibility laboratory that disagrees with a contractor's cost determination under this section is entitled to a contractor hearing, in accordance with the procedures set forth in §§ 405.1811 through 405.1833 of this chapter.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–27523 Filed 12–17–21; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 86 Monday,
No. 245 December 27, 2021

Part III

Department of Defense

Department of the Army, Corps of Engineers

33 CFR Chapter II

Reissuance and Modification of Nationwide Permits; Final Rule

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Chapter II

[Docket Number: COE–2020–0002]

RIN 0710–AB29

Reissuance and Modification of Nationwide Permits

AGENCY: Army Corps of Engineers, DoD.

ACTION: Final rule.

SUMMARY: Nationwide Permits (NWPs) authorize certain activities under Section 404 of the Clean Water Act and Section 10 of the Rivers and Harbors Act of 1899 that have no more than minimal individual and cumulative adverse environmental effects. In a proposed rule published in the September 15, 2020, issue of the **Federal Register**, the Corps proposed to reissue 52 existing NWPs and issue five new NWPs, plus the NWP general conditions and definitions. In a final rule published in the January 13, 2021, issue of the **Federal Register**, the Corps reissued 12 of the 52 existing NWPs and four of the five new NWPs, as well as the NWP general conditions and definitions. In this final rule, the Corps is reissuing the remaining 40 existing NWPs and issuing the remaining one new NWP. The NWP general conditions and definitions published in the January 13, 2021, issue of the **Federal Register** apply to the 41 NWPs reissued or issued in this final rule.

DATES: The 41 NWPs in this final rule go into effect on February 25, 2022. The 41 NWPs in this final rule expire on March 14, 2026.

ADDRESSES: U.S. Army Corps of Engineers, Attn: CECW–CO–R, 441 G Street NW, Washington, DC 20314–1000.

FOR FURTHER INFORMATION CONTACT: Mr. David Olson at 202–761–4922 or access the U.S. Army Corps of Engineers Regulatory Home Page at *https://www.usace.army.mil/Missions/Civil-Works/Regulatory-Program-and-Permits/.*

SUPPLEMENTARY INFORMATION:

Table of Contents

List of Acronyms

BMP Best Management Practice
CEQ Council on Environmental Quality
CWA Clean Water Act
DA Department of the Army
EFH Essential Fish Habitat
ESA Endangered Species Act
FWS U.S. Fish and Wildlife Service
GC General Condition
NEPA National Environmental Policy Act
NHPA National Historic Preservation Act
NMFS National Marine Fisheries Service
NPDES National Pollutant Discharge Elimination System
NWP Nationwide Permit
PCN Pre-construction Notification
RGL Regulatory Guidance Letter

List of Nationwide Permits Issued in This Final Rule

I. Background

A. General

The U.S. Army Corps of Engineers (Corps) issues nationwide permits (NWPs) to authorize activities under Section 404 of the Clean Water Act (33 U.S.C. 1344) and Section 10 of the Rivers and Harbors Act of 1899 (33 U.S.C. 403), where those activities will result in no more than minimal individual and cumulative adverse environmental effects. NWPs were first issued by the Corps in 1977 (42 FR 37122) to authorize categories of activities that have minimal adverse effects on the aquatic environment with conditions to minimize those adverse effects, without requiring individual permits for those activities. After 1977, NWPs have been issued or reissued in 1982 (47 FR 31794), 1984 (49 FR 39478), 1986 (51 FR 41206), 1991 (56 FR 59110), 1995 (60 FR 38650), 1996 (61 FR 65874), 2000 (65 FR 12818), 2002 (67 FR 2020), 2007 (72 FR 11092), 2012 (77 FR 10184), 2017 (82 FR 1860), and 2021 (86 FR 2744).

Section 404(e) of the Clean Water Act provides the statutory authority for the Secretary of the Army, after notice and opportunity for public hearing, to issue general permits on a nationwide basis for any category of activities involving discharges of dredged or fill material into waters of the United States that will cause only minimal individual and cumulative adverse environmental effects for a period of no more than five years after the date of issuance (33 U.S.C. 1344(e)). The Secretary's authority to issue permits has been

delegated to the Chief of Engineers and designated representatives of the Chief of Engineers. Nationwide permits are a type of general permit issued by the Chief of Engineers and are designed to regulate with little, if any, delay or paperwork certain activities in federally jurisdictional waters and wetlands, where those activities would have no more than minimal adverse environmental impacts (see 33 CFR 330.1(b)). The categories of activities authorized by NWPs must be similar in nature, cause only minimal adverse environmental effects when performed separately, and have only minimal cumulative adverse effect on the environment (see 33 U.S.C. 1344(e)(1)). NWPs can be issued for a period of no more than 5 years (33 U.S.C. 1344(e)(2)), and the Corps has the authority to modify, reissue, revoke, or suspend the NWPs before they expire. NWPs can also be issued to authorize activities pursuant to Section 10 of the Rivers and Harbors Act of 1899 (see 33 CFR 322.2(f)). The NWP program is designed to provide timely authorizations for the regulated public while protecting the Nation's aquatic resources.

On September 15, 2020, the Corps published a proposed rule in the **Federal Register** (85 FR 57298) to reissue 52 existing NWPs with modifications, to issue five new NWPs, and to reissue the NWP general conditions and definitions with modifications. On January 13, 2021, the Corps published a final rule in the **Federal Register** (86 FR 2744). In that final rule, the Corps reissued the following NWPs: NWP 12 (oil or natural gas pipeline activities); NWP 21 (surface coal mining activities); NWP 29 (residential developments); NWP 39 (commercial and institutional developments); NWP 40 (agricultural activities); NWP 42 (recreational facilities); NWP 43 (stormwater management facilities); NWP 44 (mining activities); NWP 48 (commercial shellfish mariculture activities); NWP 50 (underground coal mining activities); NWP 51 (land-based renewable energy generation facilities); and NWP 52 (water-based renewable energy generation pilot projects). The Corps issued four new NWPs: NWP 55 (seaweed mariculture activities); NWP 56 (finfish mariculture activities); NWP 57 (electric utility line and telecommunications activities); and NWP 58 (utility line activities for water and other substances). In the final rule published on January 13, 2021, the Corps stated that it would issue a separate final rule for its decisions on the proposed reissuance of the other 40 proposed NWPs and the issuance of proposed new NWP E for water reclamation and reuse facilities.

The 16 NWPs issued or reissued in the final rule that was published in the January 13, 2021, issue of the **Federal Register** expire on March 14, 2026. The 41 NWPs published in today's final rule will also expire on March 14, 2026, so that all of the NWPs issued or reissued in 2021 expire on the same date. Under Section 404(e) of the Clean Water Act (33 U.S.C. 1344(e)), an NWP cannot be issued for a period of more than five years, and the Corps has discretion to establish an expiration date for an NWP that is less than five years after the date the NWP goes into effect. Establishing the same expiration date for 16 NWPs issued in January 2021 and the 41 NWPs issued in today's final rule will help provide consistency and clarity to the regulated public and the Corps, and align all of the NWPs in terms of scheduling the next rulemaking to issue or reissue the NWPs. At its discretion, the Corps may rescind, revise, or suspend one or more NWPs prior to that time.

Consistent with E.O. 13990, Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis, the Army is also considering whether additional steps should be taken to ensure the Nationwide Permits program aligns with this Administration's policies and priorities moving forward.

Nationwide permits authorize categories of activities that are similar in nature and will cause only minimal adverse environmental effects when performed separately, and will have only minimal cumulative adverse effect on the environment. See 33 U.S.C. 1344(e)(1). The phrase ''minimal adverse environmental effects when performed separately'' refers to the direct and indirect adverse environmental effects caused by a specific activity authorized by an NWP. The phrase ''minimal cumulative adverse effect on the environment'' refers to the collective direct and indirect adverse environmental effects caused by all the activities authorized by a particular NWP during the time period when the NWP is in effect (a period of no more than 5 years) in a specific geographic region (*e.g.,* 40 CFR 230.7(b)(3)). These concepts are defined in paragraph 2 of section D, ''District Engineer's Decision.'' The appropriate geographic area for assessing cumulative effects is determined by the decision-making authority for the general permit (generally, the district engineer).

Some NWPs include pre-construction notification (PCN) requirements. PCNs give the Corps the opportunity to evaluate certain proposed NWP activities on a case-by-case basis to ensure that they will cause no more than minimal adverse environmental effects, individually and cumulatively. Except for activities conducted by non-federal permittees that require PCNs under paragraph (c) of the ''Endangered Species'' and ''Historic Properties'' general conditions (general conditions 18 and 20, respectively), if the Corps district does not respond to the PCN within 45 days of a receipt of a complete PCN, the activity is deemed authorized by the NWP (see 33 CFR 330.1(e)(1)).

In fiscal year 2018, the average processing time for an NWP PCN was 45 days and the average processing time for a standard individual permit was 264 days. This difference in processing time can incentivize project proponents to reduce the adverse effects of their planned activities that would otherwise require an individual permit under Section 404 of the Clean Water Act and/or Section 10 of the Rivers and Harbors Act of 1899, in order to qualify for NWP authorization. This reduction in adverse effects can therefore reduce a project's impact on the Nation's aquatic resources.

There are 38 Corps district offices and 8 Corps division offices. The district offices administer the NWP program on a day-to-day basis by reviewing PCNs for proposed NWP activities. The division offices oversee district offices and are managed by division engineers. Division engineers have the authority, after public notice and comment, to modify, suspend, or revoke NWP authorizations on a regional basis to take into account regional differences among aquatic resources and to ensure that the NWPs authorize only those activities that result in no more than minimal individual and cumulative adverse environmental effects in a region (see 33 CFR 330.5(c)). When a Corps district receives a PCN, the district engineer reviews the PCN and determines whether the proposed activity will result in no more than minimal individual and cumulative adverse environmental effects, consistent with the criteria in paragraph 2 of section D, ''District Engineer's Decision.'' At this point, the district engineer may add conditions to the NWP authorization to ensure that the verified NWP activity results in no more than minimal individual and cumulative adverse environmental effects and that it is not contrary to the public interest, consistent with processes and requirements set out in 33 CFR 330.5(d). See section II.G for more

information on regional conditions for the NWPs.

For some NWPs, when submitting a PCN, an applicant may request a waiver for a particular limit specified in the NWP's terms and conditions. If the applicant requests a waiver of an NWP limit and the district engineer determines, after coordinating with the resource agencies under paragraph (d) of NWP general condition 32, that the proposed NWP activity will result in no more than minimal adverse environmental effects, the district engineer may grant such a waiver. Following the conclusion of the district engineer's review of a PCN, the district engineer prepares an official, publicly available decision document. This document discusses the district engineer's findings as to whether a proposed NWP activity qualifies for NWP authorization, including compliance with all applicable terms and conditions, and the rationale for any waivers granted, and activity-specific conditions needed to ensure that the activity being authorized by the NWP will have no more than minimal individual and cumulative adverse environmental effects and will not be contrary to the public interest (see § 330.6(a)(3)(i)).

The case-by-case review of PCNs often results in district engineers adding activity-specific conditions to NWP authorizations to ensure that the adverse environmental effects are no more than minimal. These can include permit conditions such as time-of-year restrictions and/or use of best management practices and/or compensatory mitigation requirements to offset authorized losses of jurisdictional waters and wetlands so that the net adverse environmental effects caused by the authorized activity are no more than minimal. Any compensatory mitigation required for NWP activities must comply with the Corps' compensatory mitigation regulations at 33 CFR part 332. Review of a PCN may also result in the district engineer asserting discretionary authority to require an individual permit from the Corps for the proposed activity, if the district engineer determines, based on the information provided in the PCN and other available information, that the adverse environmental effects will be more than minimal, or otherwise determines that ''sufficient concerns for the environment or any other factor of the public interest so requires'' consistent with 33 CFR 330.4(e)(2)).

During the review of PCNs, district engineers assess cumulative adverse environmental effects caused by NWP activities at an appropriate regional scale. Cumulative effects are the result of the accumulation of direct and indirect effects caused by multiple activities that persist over time in a particular geographic area (MacDonald 2000), such as a watershed or ecoregion (Gosselink and Lee 1989). Therefore, the geographic and temporal scales for cumulative effects analysis are larger than the analysis of the direct and indirect adverse environmental effects caused by specific NWP activities. For purposes of the NWP program, cumulative effects are the result of the combined effects of activities authorized by NWPs during the period the NWPs are in effect. The cumulative effects are assessed against the current environmental setting (environmental baseline) to determine whether the cumulative adverse environmental effects are more than minimal. The district engineer uses his or her discretion to determine the appropriate regional scale for evaluating cumulative effects.

For the NWPs, the appropriate regional scale for evaluating cumulative effects may be a waterbody, watershed, county, state, or a Corps district, as appropriate. The appropriate regional scale is dependent, in part, on where the NWP activities are occurring. For example, for NWPs that authorize structures and/or work in navigable waters of the United States under Section 10 of the Rivers and Harbors Act of 1899, the appropriate geographic region for assessing cumulative effects may be a specific navigable waterbody or a seascape. For NWPs that authorize discharges of dredged or fill material into non-tidal jurisdictional wetlands and streams, the appropriate geographic region for assessing cumulative effects may be a watershed, county, state, or Corps district. The direct individual adverse environmental effects caused by activities authorized by NWPs are evaluated within the project footprint, and the indirect individual adverse environmental effects caused by activities authorized by NWPs are evaluated within the geographic area to which those indirect effects extend.

When the district engineer reviews a PCN and determines that the proposed activity qualifies for NWP authorization, the district engineer will issue a written NWP verification to the permittee (see 33 CFR 330.6(a)(3)). If an NWP verification includes multiple authorizations using a single NWP (*e.g.,* linear projects with crossings of separate and distant waters of the United States authorized by NWPs 12, 14, 57, or 58) or non-linear projects authorized with two or more different NWPs (*e.g.,* an NWP 28 for reconfiguring an existing marina basin plus an NWP 19 for minor dredging within that marina basin), the district engineer will evaluate the cumulative effects of the applicable NWP authorizations within the geographic area that the district engineer determines is appropriate for assessing cumulative effects caused by activities authorized by that NWP. As discussed above, the geographic area may be a waterbody, watershed, county, state, Corps district, or other geographic area such as a seascape.

The Corps' regulations for its ''public interest review'' at 33 CFR 320.4(a)(1) require consideration of cumulative impacts for the issuance of DA permits. Since the required public interest review and 404(b)(1) Guidelines cumulative effects analyses are conducted by Corps Headquarters in its decision documents for the issuance of the NWPs, district engineers do not need to do comprehensive cumulative effects analyses for NWP verifications. For an NWP verification, the district engineer needs only to include a statement in the administrative record stating whether the proposed activity to be authorized by an NWP, plus any required mitigation, will result in no more than minimal individual and cumulative adverse environmental effects. If the district engineer determines, after considering mitigation, that a proposed NWP activity will result in more than minimal cumulative adverse environmental effects, the district engineer will exercise discretionary authority and require an application for an individual permit for the proposed activity that requires Department of the Army (DA) authorization.

There may be activities authorized by NWPs that cross more than one Corps district or more than a single state. On May 15, 2018, the Director of Civil Works at Corps Headquarters issued a Director's Policy Memorandum titled: ''Designation of a Lead USACE District for Permitting of Non-USACE Projects Crossing Multiple Districts or States.'' [1] This Director's Policy Memorandum identified lead districts for states that have more than one Corps district and established a policy for designating a lead district for activities that require DA permits that cross district or state boundaries. Under this policy, when the Corps receives an NWP PCN or individual permit application for such activities, a lead Corps district will be designated by the applicable Corps

[1] This document is available at: *https://usace.contentdm.oclc.org/digital/collection/p16021coll11/id/2757/* (accessed 3/12/2020).

division office(s) using the criteria in the 2018 Director's Policy Memorandum, and that district will be responsible for serving as a single point of contact for each permit applicant, forming a Project Delivery Team comprising representatives of each of the affected districts, ensuring consistent reviews by the affected districts, and taking responsibility for identifying and resolving inconsistencies that may arise during the review. The list of lead districts for states is also used during the regional conditioning process for the NWPs. For that process the lead district is responsible for coordinating the development of the regional conditions and preparing the supplemental documents required by 33 CFR 330.5(c)(1)(iii).

B. Overview of Proposed Rule

On September 15, 2020, the Corps published in the **Federal Register** (85 FR 57298) a proposed regulation to reissue with modification the existing NWPs and associated general conditions and definitions and to create five new NWPs (2020 Proposal). The Corps provided a 60-day public comment period which closed on November 16, 2020. Among other things, the Corps proposed the following: (1) To reissue all existing permits (some with proposed modifications); (2) to issue two new NWPs to authorize certain categories of mariculture activities (*i.e.,* seaweed and finfish mariculture) that are not currently authorized by NWP 48; (3) to issue three NWPs that authorize separate categories of utility line based on the substances they convey; (4) to issue a new NWP which would authorize discharges of dredged or fill material into jurisdictional waters for the construction, expansion, and maintenance of water reuse and reclamation facilities; and (5) to remove the 300 linear foot limit for losses of stream bed from 10 NWPs (NWPs 21, 29, 39, 40, 42, 43, 44, 50, 51, and 52). The Corps requested comment on these and all other aspects of the proposal. The final rule published in the January 13, 2021, issue of the **Federal Register** (86 FR 2744) finalized 12 of the existing permits and addressed items (2), (3), and (5), as well as the NWP general conditions and definitions.

C. Overview of This Final Rule

This final rule reissues the 40 existing NWPs that were previously issued in the January 6, 2017, final rule (82 FR 1860) but not finalized on January 13, 2021 and issues one new NWP (NWP 59 for water reclamation and reuse facilities). This final rule does not address the 16 NWPs, general conditions, and definitions that were finalized on January 13, 2021. In response to the 2020 Proposal, the Corps received approximately 22,700 comments. Those comments relating to the January 13, 2021 final rule were addressed as part of that action; those comments relating to the NWPs in this final rule are discussed below together with the modifications made in response to those comments.

The January 13, 2021, final rule addressed the comments received in response to the 2020 Proposal on the NWP general conditions and definitions. The NWP general conditions and definitions from the final rule published in the January 13, 2021, issue of the **Federal Register** apply to the NWPs published in today's final rule. The text of the NWP general conditions and definitions are provided in the January 13, 2021, final rule on pages at 86 FR 2867–2877. The 41 NWPs in today's final rule expire on March 14, 2026, the same date as the 16 NWPs published in the January 13, 2021, issue of the **Federal Register** expire.

D. Status of Existing Permits

When the Corps modifies existing NWPs, the modified NWPs replace the prior versions of those NWPs so that there are not two sets of NWPs in effect at the same time. Having two sets of NWPs in effect at the same time would create regulatory uncertainty if each set of those NWPs has different limits, requirements, and conditions because permittees may be unclear as to which limits, requirements, and conditions apply to their authorized activities. In addition, differences in NWP limits, requirements, and conditions between two sets of NWPs can create challenges for district engineers in terms of enforcement and compliance efforts.

The Corps is modifying the expiration date for 40 existing NWPs (*i.e.,* NWPs 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 13, 14, 15, 16, 17, 18, 19, 20, 22, 23, 24, 25, 27, 28, 30, 31, 32, 33, 34, 35, 36, 37, 38, 41, 45, 46, 49, 53, and 54) that are issued in this final rule to the day before February 25, 2022. The expiration date for the 40 existing NWPs and the new NWP issued in this final rule is March 14, 2026.

Under 33 CFR 330.6(a)(3)(ii), if the NWP is reissued without modification or the activity complies with any subsequent modification of the NWP authorization, the NWP verification letter (*i.e.,* the written confirmation from the district engineer that the proposed activity is authorized by an NWP) should include a statement that the verification will remain valid for a period of time specified in the verification letter. The specified period of time is usually the expiration date of the NWP. In other words, if the previously verified activity continues to qualify for NWP authorization under any of the 40 existing NWPs reissued in this final rule, that verification letter continues to be in effect until March 18, 2022, unless the district engineer specified a different expiration date in the NWP verification letter. For most activities authorized by the 2017 NWPs, where the district engineer issued an NWP verification letter, the verification letter identified March 18, 2022, as the expiration date. As long as the verified NWP activities continue to comply with the terms and conditions of the 40 existing NWPs reissued in this final rule, those activities continue to be authorized by the applicable NWP(s) until March 18, 2022, unless a district engineer modifies, suspends, or revokes a specific NWP authorization.

Under 33 CFR 330.6(b), Corps Headquarters may modify, reissue, suspend, or revoke the NWPs at any time. Activities that were authorized by the 2017 NWPs, but no longer qualify for authorization under any of the 40 existing NWPs that are reissued in this final rule, continue to be authorized by the 2017 NWP(s) for 12 months as long as those activities have commenced (*i.e.,* are under construction) or are under contract to commence in reliance upon an NWP prior to the date on which the NWP expires. That authorization is contingent on the activity being completed within twelve months of the date of an NWP's expiration, modification, or revocation, unless discretionary authority has been exercised by a division or district engineer on a case-by-case basis to modify, suspend, or revoke the authorization in accordance with 33 CFR 330.4(e) and 33 CFR 330.5(c) or (d). This provision applies to activities that were previously verified by the district engineer as qualifying for NWP authorization, but no longer qualify for NWP authorization under the modified or reissued NWP.

The 41 NWPs issued in this final rule go into effect on February 25, 2022. The 2017 versions of the 40 existing NWPs reissued in this final rule expire on the day before February 25, 2022. The 40 existing NWPs reissued in this final rule and the new NWP issued in this final rule (*i.e.,* NWP 59) expire on March 14, 2026.

E. Nationwide Permit Verifications

Certain NWPs require the permittee to submit a PCN, and thus request confirmation from the district engineer

prior to commencing the proposed NWP activity, to ensure that the NWP activity complies with the terms and conditions of the NWP, including any conditions the district engineer adds to the NWP authorization in accordance with 33 CFR 330.6(a)(3)(i). The requirement to submit a PCN is identified in the NWP text, as well as certain general conditions. General condition 18 requires non-federal permittees to submit PCNs for any proposed activity that might affect Endangered Species Act (ESA)-listed species (or species proposed for listing) or designated critical habitat (or critical habitat proposed for such designation), if listed species (or species proposed for listing) or designated critical habitat (or critical habitat proposed for such designation) are in the vicinity of the proposed activity, or if the proposed activity is located in critical habitat or critical habitat proposed for such designation. General condition 20 requires non-federal permittees to submit PCNs for any proposed activity that might have the potential to cause effects to any historic properties listed in, determined to be eligible for listing in, or potentially eligible for listing in, the National Register of Historic Places.

In the PCN, the project proponent must specify which NWP or NWPs the project proponent wants to use to provide the required DA authorization under Section 404 of the Clean Water Act and/or Section 10 of the Rivers and Harbors Act of 1899. For voluntary NWP verification requests (where a PCN is not required), the request should also identify the NWP(s) the project proponent wants to use. The district engineer should verify the activity under the NWP(s) requested by the project proponent, as long as the proposed activity complies with all applicable terms and conditions, including any applicable regional conditions imposed by the division engineer. All NWPs have the same general requirements: That the authorized activities may only cause no more than minimal individual and cumulative adverse environmental effects. Therefore, if the proposed activity complies with the terms and all applicable conditions of the NWP the applicant wants to use, then the district engineer should issue the NWP verification unless the district engineer exercises discretionary authority and requires an individual permit. If the proposed activity does not meet the terms and conditions of the NWP identified in the applicant's PCN, and that activity meets the terms and conditions of another NWP identified by the district engineer, the district engineer will process the PCN under the NWP identified by the district engineer. If the district engineer exercises discretionary authority, the district engineer should explain the reasons for determining that the proposed activity raises sufficient concern for the environment or otherwise may be contrary to the public interest.

PCN requirements may be added to NWPs by division engineers through regional conditions to require PCNs for additional activities. For an activity where a PCN is not required, a project proponent may submit a PCN voluntarily, if the project proponent wants written confirmation that the activity is authorized by an NWP. Some project proponents submit permit applications without specifying the type of authorization they are seeking. In such cases, the district engineer will review those applications and determine if the proposed activity qualifies for NWP authorization or another form of DA authorization, such as a regional general permit (see 33 CFR 330.1(f)).

In response to a PCN or a voluntary NWP verification request, the district engineer reviews the information submitted by the prospective permittee. If the district engineer determines that the activity complies with the terms and conditions of the NWP, the district engineer will notify the permittee. Activity-specific conditions, such as compensatory mitigation requirements, may be added to an NWP authorization to ensure that the activity to be authorized under the NWP will result in no more than minimal individual and cumulative adverse environmental effects and will not be contrary to the public interest. The activity-specific conditions are incorporated into the NWP verification, along with the NWP text and the NWP general conditions. In general, NWP verification letters will expire on the date the NWP expires (see 33 CFR 330.6(a)(3)(ii)), although district engineers have the authority to issue NWP verification letters that will expire before the NWP expires, if it is in the public interest to do so.

If the district engineer reviews the PCN or voluntary NWP verification request and determines that the proposed activity does not comply with the terms and conditions of an NWP, the district engineer will notify the project proponent and provide instructions for applying for authorization under a regional general permit or an individual permit. District engineers will respond to NWP verification requests, submitted voluntarily or as required through PCNs, within 45 days of receiving a complete PCN. Except for NWP 49, and for proposed NWP activities that require ESA Section 7 consultation and/or NHPA Section 106 consultation, if the project proponent has not received a reply from the Corps within 45 days, the project proponent may assume that the project is authorized, consistent with the information provided in the PCN. For NWP 49, and for proposed NWP activities that require ESA Section 7 consultation and/or NHPA Section 106 consultation, the project proponent cannot begin work before receiving a written NWP verification. If the project proponent requested a waiver of a limit in an NWP, the waiver is not granted unless the district engineer makes a written determination that the proposed activity will result in no more than minimal individual and cumulative adverse environmental effects and issues an NWP verification.

II. Discussion of Public Comments

A. Overview

In response to the 2020 Proposal, the Corps received approximately 22,700 comment letters, of which approximately 22,330 were form letters. In addition to the various form letters, the Corps received a few hundred individual comment letters. Those individual comment letters, as well as examples of the various form letters, are posted in the *www.regulations.gov* docket (COE–2020–0002) for this rulemaking action. The Corps reviewed and fully considered all comments received in response to the 2020 Proposal. The Corps' responses to the comments received on the proposed removal of the 300 linear foot limit for losses of stream bed from 10 existing NWPs, the proposed changes to NWPs 21 and 50, the proposed reissuance of NWP 48, the proposed reissuance of NWP 12, and the proposed issuance of four new NWPs (NWPs 55, 56, 57, and 58) are summarized and addressed in the final rule published in the January 13, 2021, issue of the **Federal Register** (86 FR 2744). The sections below discuss the comments received and the Corps responses on the 40 existing NWPs and one new NWP being finalized in this rule.

B. Responses to General Comments

A summary of general comments submitted to the Corps in response to the 2020 Proposal, and responses to those general comments, are provided in the final rule published in the January 13, 2021, issue of the **Federal Register** at 86 FR 2750–2753.

(1) Status of Existing Permits

In response to the 2020 Proposal, the Corps received comments concerning the status of existing NWP authorizations and how the issuance of the final rule may affect those existing authorizations. The Corps also invited public comment on changing the expiration date for the 2017 NWPs to avoid having two sets of NWPs in effect at the same time. These comments were summarized and addressed in the final rule published in the January 13, 2021, issue of the **Federal Register** at 86 FR 2753–2754.

(2) Pre-Construction Notification Requirements

Comments on PCN requirements for the NWPs in the 2020 Proposal were addressed in the final rule published in the January 13, 2021, issue of the **Federal Register** at 86 FR 2754–2755.

(3) Climate Change

Comments on climate change and the NWPs in the 2020 Proposal were addressed in the final rule published in the January 13, 2021, issue of the **Federal Register** at 86 FR 2755. The Corps recognizes the importance of climate change resiliency and both mitigation and adaptation efforts to address climate change. The Corps discusses climate change in the context of the NWP reissuance in each of the national decision documents for the 41 NWPs. Some activities authorized by various NWPs may be associated with energy production (including the energy production through solar, wind, and other renewable resources), distribution, and use, while other activities authorized by the NWPs may contribute to adaptation to climate change and help increase the resilience of communities to the adverse effects of climate change.

(4) Environmental Justice

In response to the 2020 Proposal, the Corps received comments concerning environmental justice and how it was considered during development of the final rule. The Corps recognizes the importance of environmental justice to the Administration and incorporated consideration of impacts to communities with environmental justice interests to the extent practicable within its regulatory authorities in the issuance of this rule. The NWPs issuance are not expected to have any discriminatory effect or disproportionate negative impact on any community or group, and therefore are not expected to cause any disproportionately high and adverse impacts to minority or low-income communities. The NWPs issued in this final rule can be used by communities with environmental justice interests that want to conduct activities that require DA authorization that will help improve environmental quality within their communities (*e.g.,* NWP 13 for bank stabilization activities; NWP 27 for aquatic habitat restoration, establishment, and enhancement activities; NWP 31 for the maintenance of existing flood control facilities; and NWP 38 for hazardous and toxic waste clean-up activities).

C. Comments on Regional Conditioning of Nationwide Permits

Under Section 404(e) of the Clean Water Act, NWPs can only be issued for those activities that result in no more than minimal individual and cumulative adverse environmental effects. For activities that require authorization under Section 10 of the Rivers and Harbors Act of 1899 (33 U.S.C. 403), the Corps' regulations at 33 CFR 322.2(f) have a similar requirement. Since it can be difficult for the Corps to draft national NWPs in such a way that they account for regional differences, an important mechanism for ensuring compliance with these requirements is regional conditions imposed by division engineers to address local environmental concerns. Effective regional conditions help protect local aquatic ecosystems and other resources and help ensure that the NWPs authorize only those activities that result in no more than minimal individual and cumulative adverse effects on the environment and are not contrary to the public interest.

Prior to the effective date of the 41 NWPs published in this final rule, division engineers will complete supplemental documents for these NWPs, which will include the final regional conditions for these NWPs. Concurrent with the publication of the 2020 Proposal in the **Federal Register**, Corps districts issued public notices seeking comment on proposed regional conditions for the proposed NWPs. The division engineers' supplemental documents for the 41 NWPs will summarize the comments Corps districts received on the proposed regional conditions for those NWPs, provide responses to those comments, and provide the division engineers' decisions on whether to approve some or all of the regional conditions that were proposed by district engineers in their public notices. After the division engineers approve the regional conditions and sign the supplemental documents for these 41 NWPs, Corps districts will issue public notices on their websites announcing the final Corps regional conditions and when those regional conditions go into effect (see 33 CFR 330.5(c)(1)(v)). Copies of the district public notices are also sent to interested parties that are on each district's public notice mailing list via email or the U.S. mail. The public notice will also describe, if appropriate, a time period to complete an authorized activity as specified by 33 CFR 330.6(b) for those who have commenced work under the NWP or are under contract to commence work under the NWP (see 33 CFR 330.5(c)(1)(iv)). A copy of all Corps regional conditions approved by the division engineers for the NWPs are forwarded to Corps Headquarters (see 33 CFR 330.5(c)(3)). Copies of district public notices announcing final regional conditions for these 41 NWPs will be posted in the *www.regulations.gov* docket for the 2021 NWPs (docket number COE–2020–0002), under Supporting and Related Information so that copies of all district public notices and regional conditions are available at a central location. If, during implementation of the 41 NWPs in this final rule, division or district engineers identify the need for additional regional conditions, or changes to existing regional conditions, the procedures at 33 CFR 330.5(c)(1) must be followed, including the issuance of district public notices to provide the public with the opportunity to submit comments on the proposed new regional conditions or proposed modifications to existing regional conditions.

Comments on regional conditioning for the NWPs in the 2020 Proposal were addressed in the final rule published in the January 13, 2021, issue of the **Federal Register** at 86 FR 2758–2760.

D. Response to Comments on Specific Nationwide Permits in This Final Rule

NWP 1. Aids to Navigation. The Corps did not propose any changes to this NWP. No comments were received on the proposed NWP. This NWP is reissued as proposed.

NWP 2. Structures in Artificial Canals. The Corps did not propose any changes to this NWP. No comments were received on the proposed NWP. This NWP is reissued as proposed.

NWP 3. Maintenance. The Corps proposed to modify paragraph (a) of this NWP to authorize the repair, rehabilitation, or replacement of any currently serviceable structure or fill that did not require DA authorization at the time it was constructed. The Corps also proposed to modify paragraph (a) of this NWP to authorize the placement of new or additional riprap to protect the structure, provided the placement of riprap is the minimum necessary to

protect the structure or to ensure the safety of the structure, to reinstate a provision was in the 2007 version of NWP 3 (see 72 FR 11181).

Several commenters stated that they support modifying paragraph (a) of this NWP to authorize the repair, rehabilitation, or replacement of any currently serviceable structure that did not require DA authorization of the time it was constructed. A few commenters expressed opposition to the proposed modification of this NWP and said that the text of the 2017 version of this NWP that limits maintenance to previously authorized and currently serviceable structures should be retained. Several commenters expressed opposition to the authorization of any currently serviceable fills that were installed prior to the Clean Water Act without requiring a PCN because those fills have not been evaluated under current environmental regulations. One commenter said that the maintenance of any structures or fills that existed prior to the Clean Water Act should not require any authorization from the Corps. One commenter stated that a timeframe should be added to NWP 3 to specify a maximum length of time the structure has been in disrepair in order to use this NWP to authorize maintenance of the structure.

After considering the comments received in response to the 2020 Proposal, the Corps is reissuing this NWP without modifying paragraph (a) of this NWP to authorize the repair, rehabilitation, or replacement of any currently serviceable structure that did not require DA authorization at the time it was constructed. The repair, rehabilitation, or replacement of any currently serviceable structure that did not require DA authorization of the time it was constructed may be authorized by other forms of DA authorization, such as regional general permits and individual permits.

The NWP is limited to the repair, rehabilitation, or replacement of currently serviceable structures or fills, so it is not necessary to impose a timeframe for NWP 3 eligibility during which the need for repair, rehabilitation, or replacement activity must be completed in order to be eligible for NWP 3 authorization. The term ''currently serviceable'' is defined in section F of the NWPs. This NWP does not authorize the reconstruction of structures or fills that are no longer currently serviceable. In addition, changes to a structure or fill that prompt the need for repair, rehabilitation, or replacement may occur gradually or abruptly, or at some intermediate rate. The timeframe in which the structure or fill requires some degree of repair, rehabilitation, or replacement is not as relevant to ensuring no more than minimal adverse environmental effects than the constraints imposed by the ''currently serviceable'' and ''minor deviations'' provisions of this NWP.

The Corps does not agree that PCNs should be required for maintenance activities authorized by paragraph (a) of this NWP because of the limitations in that paragraph.

One commenter stated that the text of this NWP should be modified to allow for maintenance of any existing infrastructure provided it does not change the intended use of the structure or fill. A few commenters requested clarification as to what the term ''currently serviceable structure'' means, including whether or not the structure or fill has to be operational. One commenter requested clarification on the differences between ''replacement'' and ''reconstruction.'' A few commenters asked for changes in the text of NWP 3 to clarify that any structures or fill that were previously permitted by the Corps may utilize NWP 3 for maintenance and repair activities.

This NWP authorizes the repair, rehabilitation, or replacement of existing infrastructure while allowing minor deviations due to due to changes in materials, construction techniques, requirements of other regulatory agencies, or current construction codes or safety standards. In addition, the NWP requires the structure or fill to not be put to uses that differ from the uses originally contemplated for it when the structure or fill was originally constructed. Repair, rehabilitation, or replacement activities that exceed the ''minor deviations'' provision of this NWP may be authorized by individual permits, regional general permits, or another NWP.

The term ''currently serviceable'' is currently defined in section F of the NWPs as: ''useable as is or with some maintenance, but not so degraded as to essentially require reconstruction.'' Therefore, there must be some degree of operability associated with the structure or fill in order for repair, rehabilitation, and replacement activities to be authorized by this NWP. The difference between ''replacement'' and ''reconstruction'' is based on the concept of ''currently serviceable.'' A currently serviceable structure or fill retains some degree of operability but can be replaced before it degrades to the extent where it is no longer operable (*i.e.,* incapable of performing its intended function). In contrast, a structure or fill that is no longer capable of providing any degree of operability would have to be reconstructed to perform its intended function. This NWP can be used to repair, rehabilitate, or replace existing, currently serviceable structures or fills as long as the proposed activities satisfy the requirements in the text of the NWP, including any applicable NWP general conditions, regional conditions imposed by division engineers, and activity-specific conditions imposed by district engineers. The Corps declines to modify the text of this NWP to state that it can be used for maintenance and repair activities for previously permitted structures or fills because some of those maintenance and repair activities might not qualify for NWP 3 authorization and may require individual permits or other forms of DA authorization.

One commenter expressed opposition to authorizing the rehabilitation or replacement of structures that are derelict or not operational without a PCN and analyses of individual cumulative effects. One commenter recommended modifying this NWP to authorize regular maintenance of drainages to reduce exposed pipelines and pipeline spans. One commenter stated that without individual permit review, the Corps has no way of knowing if the structures are being replaced in kind, and whether those structures would have adverse environmental effects. This commenter also said that there need to be practicable alternatives if adverse effects are anticipated by these activities.

This NWP does not authorize the repair, rehabilitation, or replacement of structures and fills that are no longer currently serviceable. If a derelict or non-operational structure requires repair, rehabilitation, or replacement, and those activities require DA authorization, they may be authorized by individual permits or regional general permits. Discharges of dredged or fill material into waters of the United States that are necessary to rebury pipelines exposed in drainages or repair pipeline spans that extend over drainages may be authorized by this NWP or other NWPs, such as NWP 18, which authorizes minor discharges into waters of the United States. Corps district staff may conduct compliance actions for activities authorized by NWP 3, to ensure that authorized activities comply with the conditions of the NWP, including in-kind replacement. Because this NWP is limited to the repair, rehabilitation, and replacement of existing, currently serviceable structures or fills, there are usually no practicable alternatives for repairing, rehabilitating, or replacing these structures or fills. Relocating or reconstructing the

structure or fill in a different location has the potential to result in more adverse environmental effects than the incremental impact caused by the repair, rehabilitation, or replacement of the structure or fill, and might not serve the intended purpose as the original structure or fill.

Many commenters stated that they support the proposed modification that authorizes the placement of new or additional riprap to protect the structure. Several commenters said that authorization of the placement of riprap under NWP 3 should require a PCN. Some commenters objected to this proposed modification. One commenter objected to this proposed modification, stating that it could be used to authorize substantial amounts of riprap to protect an existing structure or fill, such as a beach house. One commenter stated that the phrase ''minimum necessary'' is ambiguous and unquantifiable and NWP 3 activities should be limited to ensure that no significant adverse effects occur as a result of the placement of the riprap. One commenter said that riprap placed to protect the structure or fill should be limited to 25 cubic yards. One commenter said that riprap placed above the ordinary high water mark should be covered with topsoil and revegetated, and that stream-side areas at the ordinary high water mark should be revegetated with acceptable bioengineering techniques. A few commenters stated that using the term ''riprap'' in the proposed modification will result in preferential use of this technique when other forms of protection, such as bioengineering, may be feasible and less environmentally damaging.

After considering the comments received in response to the 2020 Proposal, the Corps is not reissuing NWP 3 with the proposed modification that would authorize the placement of new or additional riprap to protect the structure or fill, as long as the placement of riprap is the minimum necessary to protect the structure or fill and to ensure the safety of the structure or fill. The placement of new or additional riprap to protect the structure or fill may be authorized by other forms of DA authorization, such as regional general permits and individual permits. If a project proponent wants to place riprap to protect a building, such as a beach house constructed in uplands, then the project proponent can use NWP 13, which may require submittal of a PCN to the district engineer, or seek DA authorization through the individual permit process.

Riprap placed in uplands landward of the ordinary high water mark does not require DA authorization, so the Corps does not have the authority to require the permittee place topsoil in those upland areas and install plants in the topsoil. Bioengineering might not be a practicable alternative to riprap for the purposes of protecting a repaired, rehabilitated, or replaced structure or fill, or ensuring its safe operation. A permittee can choose to use bioengineering to protect a structure or fill from erosion, if appropriate, and bioengineering activities that require DA authorization may be authorized by NWP 3 if it is considered a minor deviation due to changes in materials, construction techniques, requirements of other regulatory agencies, or current construction codes or safety standards. Bioengineering for bank stabilization may also be authorized by NWP 13, which authorizes a variety of bank stabilization techniques.

A few commenters requested clarification on what constitutes a minor deviation, and what constitutes a small amount of riprap. One commenter suggested replacing the term ''small'' with ''minor'' when referring the amount of riprap that can be used to protect the structure or fill, to be consistent with the 1996 NWP. One of these commenters said that NWP 3 should have quantitative limits. One commenter requested that the Corps further restrict the NWP by adding text that states that the placement of riprap may be used to ensure the safety of the design, but not for other safety purposes.

As discussed above, the Corps is not reissuing this NWP with modifications that would authorize the placement of new or additional riprap to protect the existing structure or fill. What constitutes a ''minor deviation'' is dependent on the degree to which changes in the structure's configuration or filled area would occur as a result of the repair, rehabilitation, or replacement activity relative to the size and shape of the existing structure or fill, as well as any deviations that are necessary because of changes in materials, construction techniques, the requirements of other regulatory agencies, or current construction codes or safety standards. Because this NWP authorizes structures and work in navigable waters of the United States and discharges of dredged or fill material into waters of the United States for the repair, rehabilitation, or replacement of existing, currently serviceable structures or fills, and only allows minor deviations, it would not be appropriate to add quantitative limits to the text of the NWP other than the quantitative limits currently in paragraph (b) (*i.e.,* the 200 foot limit for the removal of accumulated sediments and debris). The safety of the structure or fill may be dependent on more than the design of the structure or fill. For example, the safety of the structure or fill may be dependent on the types of materials used for the structure or fill, to help provide greater stability and help ensure that the structure or fill withstands expected erosive forces or other forces.

Many commenters stated that they support the removal of ''previously authorized'' from the Note and replacing it with ''currently serviceable.'' Several commenters suggested retaining in the ''Note'' the text that refers to ''previously authorized'' structures or fills to allow for maintenance of previously authorized structures or fills. One commenter said that in the Note the phrase ''previously authorized'' should be replaced with the term ''existing.''

In the Note for this NWP, the Corps has retained ''previously authorized'' because the Corps is not reissuing this NWP with the proposed changes to paragraph (a), which would have authorized the repair, rehabilitation, or replacement of any currently serviceable structure or fill that did not require a permit at the time it was constructed. If the structure or fill is ''currently serviceable'' it is an existing structure or fill. Therefore, it is not necessary to replace the phrase ''previously authorized'' with ''existing.''

One commenter said that the removal of accumulated sediments within 200 feet of a structure is excessive and should be evaluated on a case-by-case basis. One commenter stated that the provisions allowing removal of sediment could result in more than minimal impacts on aquatic organisms. One commenter stated that the PCN requirement for activities authorized under (b) of this NWP for sediment and debris removal is unnecessary unless the dredged material is proposed to be redeposited or retained within waters of the United States.

Paragraph (b) authorizes the removal of accumulated sediments and debris outside the immediate vicinity of existing structures (*e.g.,* bridges, culverted road crossings, water intake structures, etc.) for a distance of no more than 200 feet from the structure. All activities authorized by paragraph (b) of this NWP require a PCN to district engineers. Therefore, district engineers will review these proposed activities to determine whether removal of accumulated sediments up to 200 feet from the structure will result in no more than minimal individual and cumulative adverse environmental

effects. The removal of accumulated sediment and debris is likely to have temporary impacts on aquatic organisms because those activities occur on a periodic basis in response to the accumulation of sediment and debris in these dynamic waterbodies. Communities of aquatic organisms are likely to recover in the waterbody between sediment and debris removal activities. Division engineers may add regional conditions to this NWP to reduce the 200-foot limit in regions where shorter limits are necessary to ensure that the adverse environmental effects caused by these activities are no more than minimal. The Corps is retaining the PCN requirement for activities authorized by paragraph (b) of this NWP because of the potential for some of these activities to result in more than minimal adverse environmental effects. Therefore, district engineers should have the opportunity to review these proposed activities so that they can exercise discretionary authority when necessary to require individual permits for certain activities.

One commenter said that rebuilding existing electric utility lines should continue to be covered under NWP 3 even though NWP 57 would also authorize these activities. Numerous commenters stated that PCNs should be required for all activities authorized by this NWP. Many commenters stated this permit causes significant adverse impacts which are a violation of the Clean Water Act, and that this NWP should be withdrawn or stricter impact limitations should be imposed. One commenter said that NWP 3 authorizes activities that are not similar in nature, which violates Section 404(e) of the Clean Water Act. One commenter stated the draft decision document does not provide enough information to determine the full extent of impacts associated with this NWP.

This NWP can be used to repair, rehabilitate, or replace electric utility lines, as well as other structures or fills, as long as those electric utility lines are currently serviceable. If the electric utility line must be rebuilt because of destruction or damage by a storm, flood, fire, or other discrete event, this NWP can be used to authorize discharges of dredged or fill material into waters of the United States or structures as well as work in navigable waters of the United States for those rebuilding activities. Those electric utility line rebuilding activities may also be authorized by NWP 57. Because this NWP authorizes structures and work in navigable waters of the United States and discharges of dredged or fill material into waters of the United States for the repair, rehabilitation, or replacement of existing, currently serviceable structures or fills, and only authorizes minor deviations, the Corps does not believe that PCNs should be required for activities authorized by paragraph (a). The activities authorized by NWP 3 are similar in nature, because they are limited to the repair, rehabilitation, and replacement of currently serviceable structures or fills, or structures or fills damaged or destroyed by storms, floods (including tidal floods), fires, or other discrete events. The current qualitative and quantitative limits in the text of this NWP are sufficient to ensure that the NWP authorizes only those activities that result in no more than minimal individual and cumulative adverse effects, and no additional limits are necessary. The final decision document for this NWP provides an assessment of activities that may be authorized by this NWP during the 5-year period it is anticipated to be in effect, as well as an evaluation of potential environmental impacts that is commensurate with the anticipated degree and severity of those environmental impacts. The decision document has been prepared in compliance with the requirements of the National Environmental Policy Act (NEPA), the Corps' public interest review regulations, and the Clean Water Act Section 404(b)(1) Guidelines.

This NWP is reissued without the proposed modifications.

NWP 4. Fish and Wildlife Harvesting, Enhancement, and Attraction Devices and Activities. The Corps did not propose any changes to this NWP. No comments were received on the proposed reissuance of this NWP. This NWP is reissued as proposed.

NWP 5. Scientific Measurement Devices. The Corps did not propose any changes to this NWP. No comments were received on the proposed reissuance of this NWP. This NWP is reissued as proposed.

NWP 6. Survey Activities. The Corps did not propose any changes to this NWP. One commenter expressed support for the reissuance of this NWP with no changes. One commenter stated that the Corps should clarify the nature and extent of seismic exploratory operations that qualify for authorization under this NWP and modify this NWP to require PCNs for all seismic exploratory operations. This commenter said that seismic exploration operations may use vehicles that can compact wetland soils, create tire ruts in wetlands, and cause regulated discharges of dredged or fill material. A few commenters said seismic exploratory operations cause adverse effects to waters of the United States, endangered species, and marine mammals, and should require authorization through individual permits. One commenter stated that if seismic testing activities continue to be authorized by this NWP, then limits should be placed on the amount of exploratory trenching. One commenter said that this NWP should be modified to impose a 25 cubic yard limit for discharges of fill material for shot holes, and that survey activities involving numerous small pads in excess of 25 cubic yards should require individual permits.

This NWP authorizes survey activities, including seismic exploratory activities, that involve structures or work in navigable waters of the United States that require DA authorization under Section 10 of the Rivers and Harbors Act of 1899 and discharges of dredged or fill material into waters of the United States that require DA authorization under Section 404 of the Clean Water Act. Seismic exploratory operations may be conducted in a manner that does not require DA authorization under any of the Corps' permitting authorities. Seismic exploratory operations may be conducted using equipment on or attached to vessels in navigable waters and vehicles used on land that involve no structures or work in navigable waters or discharges of dredged or fill material into waters of the United States. For example, seismic surveying activities in marine waters may be conducted from vessels carrying or towing seismic surveying equipment, with no structures or work requiring DA authorization under Section 10 of the Rivers and Harbors Act of 1899. Those types of seismic surveying activities in marine waters do not require DA authorization.

Land-based seismic surveying activities are often conducted from vehicles that generate the seismic waves and vehicles or other devices that carry the sensors that receive the seismic waves for analysis. Driving vehicles in wetlands may cause the formation of ruts as the wheels move through wet or moist soils. However, driving vehicles such as trucks, cars, off-road vehicles, or farm tractors through a wetland in a manner in which such vehicles is designed to be used generally is not subject to regulation under Section 404 of the Clean Water Act (see 66 FR 4568). Land-based seismic surveying activities may also be conducted by drilling shot holes and detonating explosive charges in those shot holes to produce sound that is received by sensors. If those shot holes are drilled in jurisdictional

wetlands, backfilling the shot holes in jurisdictional wetlands with fill material may require DA authorization under Section 404 of the Clean Water Act.

If survey activities proposed to be conducted by non-federal permittees involve structures or work in navigable waters of the United States and/or discharges of dredged or fill material into waters of the United States, pre-construction notification is required for the proposed NWP activity if any listed species (or species proposed for listing) or designated critical habitat (or critical habitat proposed such designation) might be affected or is in the vicinity of the activity, or if the proposed activity is located in designated critical habitat or critical habitat proposed for such designation (see paragraph (c) of general condition 18, endangered species). District engineers will review PCNs submitted under paragraph (c) of general condition 18 and determine whether ESA Section 7 consultation is required for proposed NWP 6 activities. Project proponents who undertake survey activities that may result in a take of marine mammals may be required to obtain an incidental take authorization from the National Marine Fisheries Service pursuant to the Marine Mammal Protection Act.

The Corps does not agree that quantitative limits should be placed on exploratory trenching because the NWP requires restoration of the area of waters of the United States in which the exploratory trench is dug to preconstruction elevations upon completion of the survey work. In addition, the NWP does not authorize exploratory trenching activities that drain waters of the United States. The Corps also declines to impose a 25-cubic-yard limit on discharges of dredged or fill material into waters of the United States for plugging shot holes, because plugging shot holes helps restore affected areas to pre-construction elevations. Plugging shot holes also provides safety benefits by filling holes in the soil that can cause injury to people and wildlife. This NWP has a 1/10-acre limit for losses of waters of the United States for temporary pads used for survey activities, so the Corps does not believe that an additional 25-cubic-yard limit is necessary to help ensure that this NWP authorizes only those survey activities that result in no more than minimal adverse environmental effects.

This NWP is reissued as proposed.

NWP 7. Outfall Structures and Associated Intake Structures. The Corps did not propose any changes to this NWP. One commenter stated this NWP should be reissued with no changes. This NWP is reissued as proposed.

NWP 8. Oil and Gas Structures on the Outer Continental Shelf. The Corps did not propose any changes to this NWP. One commenter stated that this NWP should be reissued with no changes. One commenter said that the Corps must analyze impacts to marine mammals through an environmental impact statement and consult with NMFS through the ESA Section 7 consultation process before verifying activities under this NWP. A commenter stated that the Corps should categorically exclude the state of Oregon from this NWP because oil and gas drilling activities in federal waters near Oregon are prohibited, and all activities authorized by this NWP should require PCNs to provide the necessary coordination between the district engineer and the state.

Project proponents that use NWP 8 to authorize oil or natural gas structures on the outer continental shelf under Section 10 of the Rivers and Harbors Act of 1899 are responsible for complying with the Marine Mammal Protection Act, including any requirement to obtain incidental take authorizations from the NMFS. When a district engineer receives a PCN for a proposed NWP 8 activity, a district engineer will evaluate potential effects of the proposed structures on marine mammals that are listed as endangered or threatened under the ESA, as well as marine mammals species proposed for listing under the ESA. The district engineer will also evaluate potential effects of the proposed structures on designated critical habitat, and if applicable, critical habitat proposed for such designation. If the district engineer determines the proposed NWP 8 activity may affect listed species or designated critical habitat, including listed marine mammals and designated critical habitat for marine mammals, he or she will initiate ESA Section 7 consultation with the NMFS and, if appropriate, the U.S. FWS, unless ESA Section 7 consultation has already been conducted by another federal agency for the proposed oil and gas structures. This NWP authorizes structures in federal waters overlying the outer continental shelf; it does not authorize structures in the territorial seas. Therefore, if a project proponent wants to conduct oil or natural gas drilling activities in the territorial seas, he or she would need to obtain DA authorization through the individual permit process, or through a regional general permit if the Corps district has issued a regional general permit that authorizes oil or gas structures in the territorial seas. All activities authorized by this NWP require PCNs, and the district engineer can elect to coordinate the review of the PCN with the state.

This NWP is reissued as proposed.

NWP 9. Structures in Fleeting and Anchorage Areas. The Corps did not propose any changes to this NWP. No comments were received on the proposed reissuance of this NWP. This NWP is reissued as proposed.

NWP 10. Mooring Buoys. The Corps did not propose any changes to this NWP. Several commenters said that PCNs should be required for all activities authorized by this NWP. Several commenters stated they oppose the installation of mooring buoys within tribal lands without coordinating with the tribes. One commenter requested clarification as to how this NWP will interface with regional conditions.

The Corps does not agree that PCNs should be required for all non-commercial, single-boat mooring buoys authorized by this NWP because the installation of these structures in navigable waters of the United States is unlikely to result in more than minimal individual and cumulative adverse environmental effects. Certain NWP general conditions, such as general condition 18 for endangered species and general condition 20 for historic properties, may trigger PCN requirements for some mooring buoys proposed to be installed by non-federal permittees. For example, under paragraph (c) of general condition 18 non-federal permittees are required to submit PCNs to the district engineer if any listed species (or species proposed for listing) or designated critical habitat (or critical habitat proposed such designation) might be affected or is in the vicinity of the proposed mooring buoy, or if the proposed mooring buoy is located in designated critical habitat or critical habitat proposed for such designation. Activities authorized by this NWP must comply with general condition 17, tribal rights. During the process for reissuing this NWP, Corps districts consulted with tribes and those consultation efforts may have resulted in regional conditions or coordination procedures with tribes to help ensure compliance with general condition 17. This NWP interfaces with regional conditions in the same manner as any other NWP interfaces with regional conditions. If a division engineer imposed a regional condition on this NWP, in order to qualify for NWP authorization, the proposed activity must comply with that regional condition as well as any requirements in the text of the NWP and applicable NWP general conditions.

This NWP is reissued as proposed.

NWP 11. Temporary Recreational Structures. The Corps did not propose any changes to this NWP. No comments were received on the proposed reissuance of this NWP. This NWP is reissued as proposed.

NWP 13. Bank Stabilization. The Corps proposed to modify this NWP by adding a ''Note'' that states that in coastal waters and the Great Lakes, living shorelines may be an appropriate option for bank stabilization, and may be authorized by NWP 54.

Many commenters objected to the proposed reissuance of NWP 13, stating that that bank stabilization using bulkheads, revetments, and other hard structures has deleterious effects on shoreline ecosystems. Several commenters stated that this NWP should not be reissued so that bank stabilization activities can be limited to bioengineering or the construction of living shorelines. Many commenters said that the proposed NWP would result in significant adverse impacts, and violate Section 404(e) of the Clean Water Act, the Clean Water Act Section 404(b)(1) Guidelines, the NEPA, and the ESA. One commenter stated that the reissuance of this NWP should require an environmental impact statement.

This NWP authorizes a wide variety of bank stabilization activities because bioengineering and living shorelines are effective bank stabilization approaches in limited circumstances. This NWP authorizes both hard bank stabilization activities (*e.g.,* revetments, riprap, bulkheads) and soft bank stabilization activities (*e.g.,* bioengineering, other forms of vegetative stabilization). Living shorelines may be authorized by NWP 54, as indicated by the Note proposed to be added to this NWP. Hard bank stabilization activities may be necessary in riverine, lacustrine, estuarine, and marine environments subject to strong erosive forces. Soft bank stabilization activities may be effective at reducing erosion in aquatic habitats subject to moderate to low erosive forces. This NWP has been issued in compliance with Section 404(e) of the Clean Water Act (including the Section 404(b)(1) Guidelines), NEPA, and the ESA. In the national decision document for the reissuance of this NWP, the Corps prepared an environmental assessment with a finding of no significant impact to comply with NEPA requirements. Therefore, the reissuance of this NWP does not require the preparation of an environmental impact statement. In the national decision document, the Corps prepared a Clean Water Act Section 404(b)(1) Guidelines compliance analysis, which also addresses the requirements of Section 404(e) of the Clean Water Act. In section 8.0 of the national decision document for this NWP, the Corps discusses compliance with the ESA, including the requirements of general condition 18 and 33 CFR 330.4(f).

Many commenters said that the secondary, indirect, and cumulative effects associated with bank stabilization activities authorized by this NWP are adverse. A few commenters stated that the activities authorized by this NWP have negative adverse effects on ESA-listed fish and their critical habitat. One commenter said that bulkheads have more than minimal cumulative adverse impacts and that the Corps should not reissue this NWP because it does not know how many NWP 13 activities occur each year. One commenter said that the activities authorized by this NWP have substantial sediment-related impacts. One commenter stated that the Corps should develop a means to measure, monitor, and enforce sediment limits.

While bank stabilization activities may have adverse effects on the aquatic environment, to be authorized by this NWP those adverse effects must be no more than minimal on an individual and cumulative basis. Activities authorized by this NWP must comply with general condition 18 and 33 CFR 330.4(f), which address compliance with the ESA. Under paragraph (c) of general condition 18, non-federal permittees are required to submit a PCN to the district engineer if any listed species (or species proposed for listing) or designated critical habitat (or critical habitat proposed such designation) might be affected by the proposed activity or is in the vicinity of the proposed activity, or if the proposed activity is located in designated critical habitat or critical habitat proposed for such designation. District engineers will review all PCNs for proposed NWP 13 activities for potential effects to species and critical habitats covered under the ESA and will initiate ESA Section 7 consultation for any proposed activity that may affect listed species or designated critical habitat, including ESA-listed fish species and their designated critical habitat.

This NWP requires a PCN for any proposed activity that: (1) Involves discharges into special aquatic sites; (2) is in excess of 500 feet in length; or (3) will involve the discharge of greater than an average of one cubic yard per running foot as measured along the length of the treated bank, below the plane of the ordinary high water mark or the high tide line. District engineers will review proposed bulkheads constructed in wetlands and other special aquatic sites, as well as proposed bulkheads that are longer than 500 feet in length or involve the discharge of greater than one cubic yard per running foot as measured along the bank. The Corps tracks the use of this NWP through the required and voluntary PCNs for proposed NWP 13 activities that are submitted to district offices. While not all proposed NWP 13 activities involving the construction or replacement of bulkheads require PCNs, consistent with other NWPs that do not require PCNs for all authorized activities the Corps estimates the number of PCN and non-PCN activities anticipated to occur during the 5-year period the NWP is expected to be in effect.

Bank stabilization activities can have adverse effects on sediment processes in aquatic ecosystems, and this NWP authorizes only those bank stabilization activities that have no more than minimal individual and cumulative adverse environmental effects. Bank stabilization activities may be necessary to reduce erosion to protect buildings and other structures, as well as infrastructure (*e.g.,* utility lines). Bank stabilization activities may also help reduce sediment loads to waterbodies, by reducing erosion caused by flowing water and other sediment inputs to waterbodies. Under its procedures at 33 CFR part 326, the Corps can take actions to address situations where permittees do not comply with the terms and conditions of this NWP, including the cubic yard limit for discharges of dredged or fill material into waters of the United States.

One commenter said that the Corps needs to consider secondary effects of structures such as bulkheads in its minimal effects determination. One commenter suggested limiting use of this NWP to emergency situations when other bank stabilization techniques, such as living shorelines and bioengineering, are not available. One commenter recommended adding emergency provisions to NWP 13. One commenter expressed opposition to the complete removal of non-native plant species.

In its national decision document for the reissuance of this NWP, including the environmental assessment, public interest review, and Clean Water Act Section 404(b)(1) Guidelines analysis, the Corps evaluates potential indirect or secondary effects caused by activities authorized by this NWP. When reviewing required PCNs, as well as voluntary PCNs, for proposed NWP 13 activities, district engineers consider the site-specific direct and indirect effects that may be caused by those activities,

as required by paragraph 2 of section D, District Engineer's Decision. As discussed above, living shorelines and bioengineering are effective bank stabilization techniques under certain circumstances, and therefore this NWP should not limit the use of hard bank stabilization measures to emergency situations.

The Corps does not believe it is necessary to add provisions to this NWP to address emergency situations. Not all activities authorized by NWP 13 require PCNs, and some emergency bank stabilization measures may be undertaken without the need to submit a PCN to the Corps. If an emergency situation arises where bank stabilization activities require review by the Corps, those bank stabilization activities may be authorized through the Corps' emergency authorization procedures at 33 CFR 325.2(e)(4). The Corps did not propose any changes to this NWP regarding the removal of non-native plant species. While paragraph (g) of this NWP requires the use of native plants appropriate for current site conditions, including salinity, for bioengineering or vegetative bank stabilization, it does not require the permittee to remove individuals of non-native plant species that may become established in the project area through natural processes.

Many commenters suggested reducing the linear foot limits of this NWP. One commenter recommended removing the 500 linear foot limit from this NWP. One commenter suggested removing the 1,000-foot limit for waivers for bulkheads, to allow district engineers to issue waivers that authorize bulkheads greater than 1,000 feet in length. One commenter stated that the waiver provision should be removed from this NWP because it includes no performance standards and it can be abused. One commenter said that the Corps should not require permits for longer reaches of stream banks that would be temporarily impacted.

The Corps is retaining the 500 and 1,000 linear foot limits in this NWP. The 500 linear foot limit can be waived by the district engineer, if he or she determines after reviewing a PCN that the proposed activity will result in no more than minimal individual and cumulative adverse environmental effects and issues a written verification for the proposed NWP activity. For proposed bulkheads, the 500 linear foot limit can be waived up to the 1,000 linear foot limit. If a project proponent wants to construct more than 1,000 linear feet of bulkhead, then he or she will need to submit an application for an individual permit, unless the Corps district has issued a regional general permit that authorizes bulkheads longer than 1,000 feet in length. Division engineers can add regional conditions to this NWP to impose lower linear foot limits on bank stabilization activities, including the maximum length for bulkheads. The only performance standard that applies to waivers of the 500 linear foot limit is requirement that the district engineer issue a written determination that concludes that the proposed activity will result in no more than minimal individual and cumulative adverse environmental effects. DA authorization is required for permanent and temporary impacts to stream banks within the Corps' jurisdiction if those impacts involve discharges of dredged or fill material into waters of the United States or structures and work in navigable waters of the United States.

A few commenters said that this NWP should not authorize discharges of dredged or fill material below the ordinary high water mark or mean high water line. One commenter suggested prohibiting building out to pre-existing bank lines. A few commenters stated that impacts to special aquatic sites should not be authorized by this NWP.

The purpose of this NWP is to authorize discharges of dredged or fill material into waters of the United States and structures and work in navigable waters of the United States for bank stabilization activities that have no more than minimal individual and cumulative adverse environmental effects. Prohibiting discharges of dredged or fill material into waters of the United States below the ordinary high water mark in jurisdictional non-tidal rivers and streams, or below the high tide line in tidal streams and other tidal waters would preclude NWP authorization for many bank stabilization activities that result in minimal individual and cumulative adverse environmental effects. In addition, such a prohibition would result in ineffective protection against erosion since flowing waters and tidal waters would be likely to undercut the bank stabilization activity. Bank stabilization activities constructed under that prohibition would likely collapse after the stream or river bank, lake shore, estuary shore, or ocean shore is undermined through erosional processes. If there are no jurisdictional wetlands landward of the bank or shore, then the Corps has no authority to prevent landowners from discharging fill material to construct buildings near the banks of streams or rivers, or the shores of lakes, estuaries, and oceans. All discharges of dredged or fill material into special aquatic sites require PCNs to the Corps, and district engineers will review those PCNs to determine whether the proposed activities will result in no more than minimal individual and cumulative adverse environmental effects. If the district engineer reviews a PCN for a proposed discharge of dredged or fill material into a special aquatic site, and after considering mitigation proposed by the applicant, determines that the proposed activity will result in more than minimal individual and cumulative adverse environmental effects, he or she will exercise discretionary authority and require an individual permit for that activity.

Many commenters said that PCNs should be required for all activities authorized by this NWP. Many commenters stated that PCNs should be required for activities less than 500 feet in length. One commenter requested clarification regarding when pre-construction notification is required for activities authorized by this NWP, because there is a perception that bank stabilization activities in excess of 500 linear feet require authorization by individual permits. One commenter said that the PCN requirement for discharges into special aquatic sites should be removed. One commenter stated that PCNs should be required for all activities authorized by this NWP to ensure that those activities will not jeopardize ESA-listed species. One commenter said that all NWP 13 activities should require agency coordination.

The Corps believes that it has established appropriate PCN thresholds for this NWP, so that PCNs are required for proposed bank stabilization activities that have the potential to result in more than minimal individual and cumulative adverse environmental effects. The PCN review process allows for case-specific review of proposed activities so that district engineers can determine whether those proposed activities can be authorized by this NWP. Division engineers can impose regional conditions on this NWP to require PCNs for proposed activities that are less than 500 linear feet in length or would involve the discharge of less than one cubic yard per running foot as measured along the length of the bank. The district engineer can waive the 500 linear foot limit if she or he determines in writing, after evaluating the PCN and any comments received during the agency coordination conducted under paragraph (d) of general condition 32, that the proposed activity will result in no more than minimal individual and

cumulative adverse environmental effects.

This NWP requires PCNs for all discharges of dredged or fill material into special aquatic sites so that district engineers can review all of these proposed activities to determine whether they will result in no more than minimal adverse environmental effects. Under paragraph (c) of general condition 18, non-federal permittees are required to submit a pre-construction notification to the district engineer if any listed species (or species proposed for listing) or designated critical habitat (or critical habitat proposed such designation) might be affected or is in the vicinity of the proposed activity, or if the proposed activity is located in designated critical habitat or critical habitat proposed for such designation. The district engineer will review the PCN and determine whether ESA Section 7 consultation or conference with the U.S. FWS and/or NMFS is required for the proposed activity. If ESA Section 7 consultation or conference is required, the activity is not authorized by NWP until the district engineer notifies the project proponent that those processes are completed. Certain activities authorized by NWP 13 require agency coordination, specifically activities for which permittees are requesting waivers of the quantitative limits of this NWP or for discharges into special aquatic sites. The Corps does not agree that agency coordination should be required for all NWP 13 activities that require pre-construction notification.

Several commenters expressed support for adding the Note to this NWP to make permittees aware of the availability of NWP 54 (Living Shorelines) for bank stabilization activities in coastal waters. Many commenters suggested modifying this NWP to require a preferential hierarchy for bioengineering and living shorelines over bank hardening activities to satisfy requirements to authorize the least environmentally damaging practicable alternative.

The Corps has added the proposed Note to this NWP. The Corps encourages waterfront property owners and other project proponents to use living shorelines, bioengineering, vegetative stabilization, and other soft bank stabilization approaches in coastal areas and other waterbodies where those methods are likely to be successful in managing erosion along coastal waters, along river and stream banks, and shorelines in lakes and other waterbodies. The use of living shorelines, bioengineering, vegetative stabilization, and other soft bank stabilization approaches can help increase the resilience of waterfront properties, as well as the structures and infrastructure located on those properties, to the adverse effects of climate change. The increased use of nature-based approaches such as living shorelines and bioengineering to bank stabilization is a priority in the Administration's climate resiliency efforts. Noting this, the Corps provides that such soft bank stabilization techniques should generally be considered first when project proponents consider the use of NWP 13. There are many factors, however, that should be taken into account in both the proposed and verified bank stabilization project.

The appropriate approach to managing shoreline or bank erosion in coastal areas and other waterbodies must be determined on a site-specific basis after considering a variety of factors. Examples of factors relevant to the planning and design of bank stabilization activities include, but are not limited to: Bank height; bank condition; the energy of the tides, waves, currents, or other water flows that the bank is exposed to; fetch; nearshore water depths; the potential for storm surges; sediment or substrate type; tidal range in areas subject to the ebb and flow of the tide; shoreline configuration and orientation; whether there is infrastructure in the vicinity of the proposed bank stabilization activity that needs to be protected; the width of the waterway; the presence of trees in the vicinity of the bank and whether those trees need to be maintained or protected; and the distance from a navigation channel or navigable fairway in the waterbody. With respect to living shorelines, factors to consider regarding the appropriateness of living shorelines to manage bank erosion in coastal areas include the fetch of the waterbody, shore morphology, depth gradients of nearshore waters, the stability of the existing substrate, tidal range, and marsh elevations (Saleh and Weinstein 2016).

Project proponents may hire coastal engineers and other consultants to help determine which bank stabilization techniques might be feasible and successful at a specific site. District engineers are available to discuss potential bank stabilization options with waterfront property owners and their consultants, including the use of living shorelines, bioengineering, and other soft bank stabilization approaches that may be effective at controlling erosion at a particular site, as well as more environmentally beneficial. The Corps cannot mandate the use of a particular bank stabilization technique at a specific site. District engineers can require minor project modifications to proposed activities to reduce adverse environmental impacts (see 33 CFR 320.4(r)(1)(i)). However, district engineers cannot require completely different designs of proposed activities that require DA authorization without agreement from the applicant. In addition to the factors identified in the previous paragraph, there are other factors to consider when selecting a bank stabilization method, including costs and maintenance requirements, which can vary substantially among different bank stabilization approaches. In addition, requiring specific approaches to bank stabilization may also negatively affect disadvantaged communities. District engineers will review PCNs for proposed bank stabilization activities, and if the district engineer determines that a proposed bank stabilization activity will result in more than minimal adverse environmental effects, the district engineer will exercise discretionary authority and require an individual permit. During the individual permit review process, an alternatives analysis is required and the alternatives evaluated during the individual permit review process may include soft bank stabilization approaches.

Waterfront property owners and other project proponents are responsible for proposing bank stabilization activities for their properties, and under the NWP program, district engineers review PCNs for those proposed activities. If a district engineer reviews a PCN for a proposed bank stabilization activity and determines that the proposed activity will result in more than minimal adverse environmental effects, the district engineer will exercise discretionary authority and require an individual permit for that proposed activity.

The Corps encourages waterfront property owners to first consider the use of living shorelines, vegetative stabilization, bioengineering, and other soft bank stabilization approaches before considering hard bank stabilization techniques such as bulkheads and revetments; however, the Corps acknowledges that living shorelines and bioengineering are not effective or appropriate approaches to bank stabilization in all conditions. For certain types of aquatic ecosystems and site conditions, such as environments subjected to high energy erosive forces, hard structural bank stabilization measures such as revetments and bulkheads may be necessary to reduce erosion and protect people, buildings,

and infrastructure. The requirement in the Clean Water Act Section 404(b)(1) Guidelines to permit the least environmentally damaging practicable alternative applies to activities authorized by individual permits, not to activities authorized by general permits. The Corps will include in their NWP 13 verification decision document a summary of the rationale for the verified bank stabilization measures reflecting the engineering, cost, technology and other considerations above, to include discussion of soft bank stabilization techniques and why it was or was not appropriate for the subject site.

One commenter said that the Corps' draft decision document for this NWP did not provide an adequate analysis of the direct, indirect, and cumulative impacts caused by these activities and did not use adequate scientific information to describe the affected environment and the impacts of bank stabilization activities. One commenter asserted that this NWP does not comply with the 404(b)(1) Guidelines. One commenter said that the Corps should prepare an environmental impact statement for the proposed reissuance of this NWP. One commenter stated that activities authorized by this NWP cause significant degradation of aquatic ecosystems. One commenter suggested that the Corps include sea level rise in its analysis of this NWP, including its assessment of cumulative impacts.

The final decision document prepared by Corps Headquarters for the reissuance of this NWP provides a general analysis of the impacts expected to be caused by activities authorized by this NWP during the 5-year period it is anticipated to be in effect. In the environmental assessment, the Corps evaluated the effects or impacts on the human environment that are reasonably foreseeable and have a reasonably close causal relationship to the activities authorized by this NWP, consistent with the Council on Environmental Quality's definition of ''effects or impacts'' at 40 CFR 1508.1(g). In the national decision document, the Corps also addressed the elements required for a Clean Water Act Section 404(b)(1) Guidelines analysis for the issuance of a general permit, including a cumulative effects analysis conducted in accordance with 40 CFR 230.7(b)(3) and a conclusion that the reissuance of this NWP would not cause or contribute to significant degradation of the aquatic environment.

The affected environment of the United States is described in section 4.0 of the national decision document, using available information at a national scale to describe the current environmental baseline. The Corps complied with the requirements of NEPA by preparing an environmental assessment with a finding of no significant impact. Therefore, an environmental impact statement is not required for the reissuance of this NWP. The national decision document for this NWP has been revised to provide more discussion of sea level rise, including the need for bank stabilization activities to protect buildings and infrastructure from increased risks of erosion that may be caused by rising sea levels. Bank stabilization activities authorized by this NWP can help protect existing buildings and infrastructure and reduce risks associated with rising sea levels, as a means of adapting to climate change. Rising sea levels are an effect of climate change.

One commenter suggested adding a definition of ''bioengineering'' to this NWP. One commenter requested that the Corps enforce current guidelines to remove non-biodegradable fabric used in previous projects. One commenter said that the Corps needs to develop functional assessment tools to better assess individual and cumulative impacts of bank stabilization on channel and floodplain processes.

The Corps declines to add a definition of ''bioengineering'' to this NWP to because adding such a definition might impose unnecessary constraints on potential bioengineering approaches to bank stabilization that may be authorized by this NWP. Bioengineering approaches can vary by region, may involve a variety of techniques and materials, and may vary by resource type. Non-biodegradable fabric may be used as a component for a variety of bank stabilization techniques and that fabric needs to permanently remain in place to control erosion at the site. Requiring the removal of fabric that is used for bank stabilization activities would likely undermine the efficacy of bank stabilization projects and their structural integrity because fabric is often necessary to ensure that soil under revetments and other bank stabilization structures is not washed away by tidal waters or by water moving through the soil to the bank or shoreline. If the soil under revetments and other bank stabilization structures is moved away from the project site, then those structures may collapse and erosion may be exacerbated. Adjacent uplands may also collapse or subside, posing a potential danger to people who live at or use the project site.

While functional assessment tools may be useful in assessing the individual and cumulative environmental impacts of bank stabilization activities within a project site, a waterbody, or within a geographic region, those environmental impacts can be assessed through other means. When reviewing PCNs for proposed NWP 13 activities, district engineers will apply the 10 criteria in paragraph 2 of section D, District Engineer's Decision to determine whether a proposed NWP 13 activity qualifies for NWP authorization. If an appropriate functional assessment is available, that tool may be used by district engineers when evaluating PCNs and determining whether a proposed bank stabilization activity qualifies for NWP 13 authorization.

This NWP is reissued as proposed.

NWP 14. Linear Transportation Projects. The Corps proposed to modify this NWP by adding ''driveways'' to the list of examples of activities authorized by this NWP.

Several commenters expressed support for the addition of ''driveways'' to the list of examples of the types of projects authorized by this NWP. One commenter said that adding ''driveways'' to the list of examples for the types of projects authorized by this NWP could confuse applicants and result in an increase of PCNs submitted to the Corps, and requested that the Corps provide a more detailed explanation of the type of driveway authorized by this NWP. A commenter said the text of this NWP should be revised to clarify if NWP 14 would be used to authorize driveways when a project proponent is using other NWPs such as NWP 29 (Residential Development) or NWP 39 (Commercial and Institutional Developments) to authorize a development project that may include one or more driveways. One commenter stated that driveways should be limited to vehicle access to a facility and not to large-scale transportation projects, with an acreage limit that applies to the driveway.

The Corps has adopted the proposed modification of this NWP to include ''driveways'' in the list of examples of the types of projects authorized by this NWP. The term ''driveways'' applies broadly to include features that are used by vehicles to move to and from buildings and other facilities, and is not limited to driveways associated with single unit or multiple unit residences, or driveways used to go to and from commercial buildings, institutional buildings, or other types of buildings. Discharges of dredged or fill material into waters of the United States for the construction or expansion of driveways may also be authorized by NWPs 29 and 39 as attendant features to residential developments and commercial and institutional developments. Adding ''driveways'' to the list of examples of

the types of projects that may be authorized by NWP 14 can provide some clarity to the regulated public because the construction of a driveway may be the only activity that requires DA authorization if a residential development or commercial or institutional development is constructed in uplands, and the driveway is needed to cross waters of the United States to provide vehicular access to the upland development.

There is usually no need to combine NWP 14 with NWP 29 or NWP 39 to authorize the construction or expansion of driveways within residential or commercial or institutional developments, unless the construction of the driveway involves discharges of dredged or fill material into waters of the United States that are not authorized by NWPs 29 or 39. For example, the construction or expansion of a driveway that crosses tidal waters or non-tidal wetlands adjacent to tidal waters, may be authorized by NWP 14 because NWPs 29 and 39 do not authorize discharges of dredged or fill material into tidal waters. A driveway serves a specific purpose that may be different than other types of linear transportation projects. Driveways are subject to the same acreage limits as other linear transportation projects authorized by this NWP, including larger scale linear transportation projects: 1/2-acre for losses of non-tidal waters of the United States and 1/3-acre for losses of tidal waters.

One commenter stated that the cumulative impacts of authorizing large residential driveways in waters of the United States threatens nearshore benthic habitat that is important to salmonids. One commenter recommended modifying this NWP to include a definition for ''stand-alone project.'' One commenter suggested modifying NWP 14 to authorize any structure or fill that would facilitate the movement of people and/or goods, including moving sidewalks, stationary sidewalks, streetcars, trams, and trollies. One commenter stated that this NWP should authorize the construction, expansion, or modification of ferry terminals.

When reviewing PCNs for proposed driveways authorized by this NWP, the district engineer will determine whether a proposed activity may affect ESA-listed species or designated critical habitat, including listed salmon species and their designated critical habitat. If the district engineer determines a proposed NWP activity may affect listed species or designated critical habitat, he or she will initiate ESA Section 7 consultation with the NMFS and/or U.S. FWS as appropriate. The proposed activity cannot be authorized by NWP until the ESA Section 7 consultation process has been concluded. A non-federal permittee must submit a pre-construction notification to the district engineer if any listed species (or species proposed for listing) or designated critical habitat (or critical habitat proposed such designation) might be affected or is in the vicinity of the activity, or if the activity is located in designated critical habitat or critical habitat proposed for such designation (see paragraph (c) of general condition 18).

The Corps declines to add a definition of ''stand-alone project'' to this NWP because that phrase is not used in this NWP. The first sentence of this NWP provides examples of linear transportation projects that may be authorized by this NWP, and those examples include railways and trails. The list of examples is not an exhaustive list, so other types of linear transportation projects that require DA authorization may be authorized by this NWP, including streetcars, trams, and trollies. Sidewalks may be authorized other NWPs, such as NWPs 29 and 39 if those sidewalks are attendant features of the types of developments authorized by those NWPs. This NWP does not authorize discharges of dredged or fill material into waters of the United States or structures or work in navigable waters of the United States for the construction, modification, expansion, or improvement of ferry terminals because ferry terminals are not linear transportation projects. A ferry terminal is a single point within a ferry transportation system, and is a non-linear feature.

One commenter said that the term ''crossing'' should be defined or changed to ''placement of dredge or fill and structures'' or ''impacts to waters of the United States.'' This commenter stated that the term ''crossing'' has been viewed strictly as a crossing or bisecting of waters of the United States rather than allowing roadway fill in a wetland along the linear transportation project since the road only filled a portion of the wetland rather than crossing it.

The NWP uses the term ''crossing'' because linear transportation projects have a point of origin and a terminal point and may involve multiple crossings of waterbodies at separate and distant locations to move people, goods, or services between the point of origin and the terminal point. A crossing does not have to bisect a water of the United States. For example, a crossing can consist of dredged or fill material placed in waters of the United States along the edge of the linear transportation project without bisecting the waterbody. A crossing constructed in such a manner can be considered to minimize impacts to waters of the United States in compliance with paragraph (a) of general condition 23, mitigation, without a loss of connectivity within the remaining extent of the waterbody. Paragraph (a) of general condition 23 requires project proponents to design and construct their NWP activities to avoid and minimize adverse effects, both temporary and permanent, to waters of the United States to the maximum extent practicable at the project site (*i.e.,* on site).

One commenter said that linear transportation projects authorized by this NWP have devastating impacts on animal populations resulting from habitat loss, habitat fragmentation, creation of migration barriers, and increased impervious surface runoff. This commenter said these impacts must be assessed through the preparation of an environmental impact statement and through ESA Section 7 consultation.

General condition 2 (aquatic life movements) states that no NWP activity may substantially disrupt the necessary life cycle movements of those species of aquatic life indigenous to the waterbody, including those species that normally migrate through the area, unless the activity's primary purpose is to impound water. General condition 2 also requires all permanent and temporary crossings of waterbodies to be suitably culverted, bridged, or otherwise designed and constructed to maintain low flows to sustain the movement of those aquatic species. For terrestrial animals, linear transportation projects can be designed and constructed to provide corridors for animal movement (*e.g.,* tunnels, bridges) so that target species can safely move from one side of the linear transportation project to the other side.

The construction of linear transportation projects may trigger a requirement by state or local governments to provide stormwater management facilities to reduce adverse effects to changes in watershed hydrology that may be caused by the construction of roads and other impervious surfaces in the watershed. Stormwater management facilities can reduce surface runoff that may adversely affect rivers, streams, and other waterbodies. District engineers will conduct ESA Section 7 consultation for proposed NWP 14 activities when they determine that those activities may affect listed species or designated critical habitat. This NWP authorizes

only activities that have no more than minimal individual and cumulative adverse environmental effects, and NEPA compliance was completed through the preparation of an environmental assessment by Corps Headquarters in the national decision document for the reissuance of this NWP. The Corps concluded the environmental assessment with a finding of no significant impact. Therefore, the reissuance of this NWP does not require the preparation of an environmental impact statement.

One commenter said the 1/2-acre limit for losses of non-tidal waters of the United States and the 1/3-acre limit for losses of tidal waters is not consistent with other NWPs. One commenter stated that both acreage limits for this NWP should be reduced to 1/10-acre. One commenter said the phrase ''minimum necessary'' is ambiguous in the context of limiting stream channel modifications and recommended limiting stream channel modifications to 300 linear feet or 1/10-acre. One commenter said that this NWP should not authorize linear projects that are more than a few hundred feet in length. One commenter expressed agreement that an individual permit is required for an entire linear project if one crossing of waters of the United States does not satisfy the terms and conditions of the NWP.

The 1/2-acre limit for losses of non-tidal waters of the United States in this NWP is consistent with the 1/2-acre limit in other NWPs that authorize discharges of dredged or fill material into non-tidal waters of the United States, such as NWP 21 (surface coal mining activities), NWP 29 (residential developments), NWP 39 (commercial and institutional developments), NWP 40 (agricultural activities), NWP 42 (recreational facilities), NWP 43 (stormwater management facilities), NWP 44 (mining activities), NWP 50 (underground coal mining activities), NWP 51 (land-based renewable energy generation facilities), and NWP 52 (water-based renewable energy generation pilot projects). The 1/3-acre limit for losses of tidal waters for NWP 14 was adopted in 1991 (see 56 FR 59142), and the 1/3-acre limit applied to losses of tidal waters and non-tidal waters. When the Corps issued 5 new NWPs and modified 6 existing NWPs to replace NWP 26 in 2000 (see 65 FR 12818), it modified NWP 14 by increasing the acreage limit for losses of non-tidal waters for public linear transportation projects to 1/2-acre. The 1/2-acre and 1/3-acre limits, plus the PCN requirements for this NWP, are sufficient to ensure that activities authorized by this NWP result in no more than minimal individual and cumulative adverse environmental effects. In addition, division engineers can add regional conditions to this NWP to lower the acreage limits in a particular geographic area to ensure compliance with the ''no more than minimal adverse environmental effects'' requirement for the NWPs.

The use of the phrase ''to the minimum necessary'' for stream channel modifications for linear transportation projects requires project proponents to minimize their stream channel modifications while providing flexibility to allow district engineers and project proponents to take into account for project-specific circumstances as well as design and construction constraints that may be imposed by site-specific conditions, including stream channel geomorphology, the topography of the surrounding area, and the purpose of the linear transportation project. Any loss of stream bed due to filling or excavation is also subject to the 1/2-acre and 1/3-acre limits of this NWP, so the Corps does not believe it is necessary to add a 300 linear foot limit for stream channel modifications. The Corps also declines to impose an overall linear foot limit to linear transportation projects since there can be substantial distances between crossings of waters of the United States, and those crossings may involve different waterbodies and watersheds. The Corps has retained Note 1 in this NWP, which references 33 CFR 330.6(d). Section 330.6(d) addresses how NWPs may or may not be combined with individual permits for activities that require DA authorization.

One commenter said that for a linear transportation project with multiple crossings of waters of the United States, the overall linear transportation project should be considered as the single and complete project, not the individual crossings of jurisdictional waters and wetlands. One commenter stated that allowing up to 1/2-acre of losses of waters of the United States for each single and complete project could result in extensive cumulative impacts and recommended that the Corps impose a single, overall limit to the entire linear transportation project. One commenter stated that linear transportation projects may cause cumulative impacts not captured in the NWP cumulative impact analysis because some activities are authorized by NWP 14 without a requirement to submit PCNs. One commenter said that allowing the expansion, modification, or improvement of previously authorized projects for linear transportation projects could result in cumulative impacts above the acreage limits and therefore these activities should only be authorized when losses of waters of the United States for the previously authorized projects plus the losses of waters of the United States for the proposed expansion, modification, or improvement project do not exceed the 1/2-acre or 1/3-acre limits. One commenter said that all crossings of waters of the United States in a major watershed should be evaluated together as a single and complete project because the cumulative impacts are to one system, or alternatively that all activities authorized by this NWP should require PCNs to allow for the evaluation of cumulative impacts.

The practice for providing NWP authorization for single and complete linear project, where each separate and distant crossing of waters of the United States may qualify for its own NWP authorization, is consistent with the Corps' NWP regulations at 33 CFR 330.2(i), which were published in the November 22, 1991, issue of the **Federal Register** (56 FR 59110)). District engineers will evaluate the separate and distant crossings of waters of the United States that require PCNs for linear transportation projects, as well as the additional information provided in the PCNs for crossings of waters of the United States authorized by NWP that do not require PCNs. Paragraph (b)(4)(i) of general condition 32 requires the prospective permittee to identify in the PCN any other NWP(s), regional general permit(s), or individual permit(s) used or intended to be used to authorize any part of the proposed project or any related activity, including other separate and distant crossings for linear projects that require DA authorization but do not require pre-construction notification. In addition, paragraph (b)(4)(ii) requires the prospective permittee to include in the PCN the quantity of anticipated losses of wetlands, other special aquatic sites, and other waters for each single and complete crossing of those wetlands, other special aquatic sites, and other waters (including those single and complete crossings authorized by an NWP but do not require PCNs). Because of the requirements of paragraph (b)(4) of general condition 32, it is not necessary to require PCNs for all activities authorized by NWP for linear transportation projects.

The district engineer will use the information in the PCN to evaluate the individual and cumulative adverse environmental effects of the proposed linear transportation project that are authorized by NWP. The district engineer determines the appropriate

geographic scale for evaluating cumulative impacts. The cumulative effects may be evaluated on a watershed-basis, or by using other types of geographic regions, such as a Corps district, state, county, or other geographic area deemed appropriate by the district engineer. Cumulative effects accrue from multiple uses of an NWP in a geographic area. Separate and distant crossings of waters of the United States for a linear transportation project may occur in different waterbodies within a single watershed, or various waterbodies in more than one watershed, depending on the length of the linear transportation project, the distribution of waterbodies in a watershed, and the size of the watershed(s). Separate and distant crossings authorized by NWP may also occur in a single waterbody (*e.g.,* a meandering stream), as long as there is sufficient distance between crossings of waters of the United States.

When evaluating PCNs for proposed NWP 14 activities, district engineers may also consider previously authorized losses of the United States for linear transportation projects when a project proponent wants to expand, modify, or improve a previously authorized linear transportation project. Since the NWPs can be issued for a period of no more than five years, the cumulative effects caused by an NWP are limited to the number of times that NWP is used during the five year period it is in effect (see 40 CFR 230.7(b)(3)). Therefore, if the proposed expansion, modification, or improvement is for a linear transportation project that was authorized in the current five-year cycle for the NWP, the district engineer should take the previously authorized losses of waters of the United States into account when determining if the proposed changes to the linear transportation project will result in no more than minimal individual and cumulative adverse environmental effects and qualify for NWP 14 authorization. On the other hand, if the proposed expansion, modification, or improvement is for a linear transportation project that was authorized by a previous version of NWP 14 that has expired, the district engineer does not need to take the previously authorized losses of waters of the United States into account, because the previously authorized activities have become part of the current environmental baseline for evaluating the individual and cumulative adverse environmental effects of the NWP currently in effect.

One commenter requested clarification regarding whether the PCN requirement for losses of greater than 1/10-acre of waters of the United States applies to the overall linear project or each single and complete project. One commenter stated that agency coordination should be required for proposed activities in special aquatic sites or that would result in the loss of greater than 1/10-acre of waters of the United States. One commenter said that agency coordination should be required for stream losses of stream bed greater than 300 linear feet.

The PCN thresholds for this NWP apply to each single and complete project authorized by NWP. However, if the linear transportation project involves multiple separate and distant crossings of waters of the United States, and some of those crossings do not require pre-construction notification, paragraph (b)(4) of general condition 32 requires the project proponent to identify the crossings authorized by NWP that do not require PCNs, as well as quantity of anticipated losses of waters of the United States expected to be caused by those non-PCN NWP activities. The Corps does not agree that agency coordination is necessary to provide the district engineer with information to assist in his or her determination whether the proposed activity qualifies for NWP authorization. District engineers will determine whether proposed NWP 14 activities qualify for NWP authorization after reviewing the information in PCNs.

One commenter stated that all linear transportation projects previously authorized by NWP 14 should require PCNs if the project proponent wants to use NWP 3 to authorize maintenance activities for the previously authorized NWP activities. One commenter said there should be more consistency between NWPs 12 and 14 in terms of acreage limits, PCN thresholds, and allowing the use of temporary mats, because both NWPs authorize single and complete linear projects with separate and distant crossings of waters of the United States that do not have independent utility.

This NWP can be used to authorize the maintenance of linear transportation projects, including the replacement of structures and fills for linear transportation projects that may not qualify NWP 3 authorization. Those replacement activities may not qualify for NWP 3 authorization because the current linear transportation project is not currently serviceable, or because the project proponent wants to change the design and/or size of the linear transportation project to accommodate changes in water flow, improve connectivity for the movement of aquatic organisms upstream and downstream of the road crossing, or for other reasons. Changing the size and/or configuration of the structures and fills for a linear transportation project may be comprised of more than a minor deviation, which may preclude the use of NWP 3 for the replacement activity. For example, replacing an undersized or perched culvert with a larger culvert structure that improves the passage of aquatic organisms and connectivity may be considered an improvement of a linear transportation project. NWP 3 may be more appropriate for certain repair, rehabilitation, or replacement activities for linear transportation projects, as well as the removal of accumulated sediment within and near water crossings. The NWP program provides flexibility to permittees to determine which applicable NWP to use to provide the required DA authorization under Section 404 of the Clean Water Act and/or Section 10 of the Rivers and Harbors Act of 1899.

The acreage limits for NWPs 12 and 14 have some similarities, with a 1/2-acre limit for losses of non-tidal waters of the United States. The 1/2-acre limit for NWP 12 also applies to tidal waters, while NWP 14 has a 1/3-acre limit for losses of tidal waters. Nationwide permits 12 and 14 have somewhat different PCN thresholds because of differences between oil or natural gas pipeline activities and linear transportation projects. Both NWPs have a PCN threshold for losses of greater than 1/10-acre of waters of the United States. Both NWP 12 and 14 have provisions authorizing the use of temporary mats, when the use of those mats requires DA authorization.

This NWP is reissued as proposed.

NWP 15. U.S. Coast Guard Approved Bridges. The Corps did not propose any changes to this NWP. No comments were received in response to the proposed reissuance of this NWP. This NWP is reissued as proposed.

NWP 16. Return Water From Upland Contained Disposal Areas. The Corps did not propose any changes to this NWP. One commenter stated that the NWP should require the applicant to ensure toxic substances are not released back into the water column through re-exposure from dredging activities. One commenter said that the applicant should properly characterize the quality and quantity of return water to ensure state water quality standards are not violated.

This NWP authorizes only the return water from upland contained disposal areas for dredged material, which is defined as a ''discharge of dredged material'' under 33 CFR 323.2(d)(1)(ii).

This NWP does not authorize the dredging activity itself. Discharges into waters of the United States require water quality certification from the appropriate certifying authority unless a waiver of the water quality certification requirement occurs. The certifying authority will determine whether a discharge into waters of the United States will comply with applicable water quality requirements.

This NWP is reissued as proposed.

NWP 17. Hydropower Projects. The Corps proposed to modify this NWP to authorize discharges of dredged or fill material into waters of the United States associated with hydropower projects with a generating capacity of less than 10,000 kilowatts (kW), to be consistent with the current definition of ''small hydroelectric power project.''

Several commenters stated they support the changing the threshold for ''small hydroelectric projects'' to 10,000 kW or less. Many commenters objected to the proposed reissuance of this NWP, stating that hydropower projects typically result in significant adverse effects and should not be authorized by an NWP. Several commenters stated that they do not support increasing the threshold for hydroelectric projects under criterion (a) of this NWP to 10,000 kW. One commenter said the Corps is not obligated to modify the NWP to be consistent with the Federal Energy Regulatory Commission's (FERC) definition of ''small hydroelectric project'' and stated that the Corps should not increase the threshold for total generating capacity to 10,000 kW.

This NWP is limited to the authorization of discharges of dredged or fill material into waters of the United States associated with the construction of hydropower facilities that satisfy criteria (a) or (b) in the first paragraph of the NWP. The FERC licenses the construction and operation of hydropower facilities, and is the lead for conducting the environmental review for these hydropower projects. Permit requirements for structures and work in navigable waters of the United States for non-federal hydropower development are met through the FERC's licensing process under the Federal Power Act of 1920, as amended. Therefore, separate authorization from the Corps under Section 10 of the Rivers and Harbors Act of 1899 is not required for structures and work in navigable waters of the United States.

Because criterion (a) of this NWP applies only to existing reservoirs, the NWP is limited to authorizing discharges of dredged or fill material into waters of the United States to install the hydropower generation unit with a total generating capacity of up to 10,000 kW in the existing reservoir. The modification of this NWP is intended to provide consistency with FERC's definition of ''small hydroelectric project'' and reduce duplication of agency reviews for these projects. In addition, hydropower is a renewable energy source and increasing the threshold for small hydroelectric projects from 5,000 kW to 10,000 kW will provide NWP authorization for activities that can help provide more electricity to a community or region, and may help decrease reliance on energy generation facilities that rely on the combustion of fossil fuels to produce electricity. Therefore, increasing the energy generation capacity of hydroelectric facilities can help reduce emissions of greenhouse gases that contribute to global climate change.

One commenter stated that activities authorized under criterion (b) of this NWP would exceed the development at existing dams and related infrastructure and would result in adverse effects. One commenter said that in certain circumstances, hydropower projects are exempt from FERC licensing and subsequently do not require authorization under Section 404 of the Clean Water Act or water quality certification from the applicable certifying authority. One commenter said that the Corps failed to provide sufficient explanation as to how the proposed change would continue to authorize activities that have no more than minimal individual and cumulative adverse environmental effects. A few commenters said that the text of the NWP should be revised to protect tribal and village fisheries. One commenter stated that the NWP should be revised to clarify that the NWP does not authorize the construction of new dams.

This NWP was issued in 1982 to reduce duplication between the reviews conducted by FERC and the Corps for small hydropower projects (see 47 FR 31798). For hydropower projects, the Corps' regulatory authority is limited to discharges of dredged or fill material into waters of the United States under Section 404 of the Clean Water Act. The FERC conducts a review when it grants a licensing exemption under the statutes identified in criterion (b) of this NWP (*i.e.,* Section 406 of the Energy Security Act of 1980 (16 U.S.C. 2705 and 2708) and Section 30 of the Federal Power Act, as amended (16 U.S.C. 823)). The NWP authorization covers the discharges of dredged or fill material into waters of the United States may be necessary to construct the hydropower project. This NWP requires pre-construction notification for all authorized activities, and district engineers will review each proposed NWP 17 activity to determine if the proposed discharge of dredged or fill material into waters of the United States will result in no more than minimal individual and cumulative adverse environmental effects. If the district engineer determines a proposed discharge of dredged or fill material into waters of the United States will result in more than minimal adverse environmental effects after considering mitigation proposed by the applicant, he or she will exercise discretionary authority and require an individual permit for the proposed activity. During the review of the PCN, the district engineer will also assess compliance with general condition 17, tribal rights. This NWP does not authorize the construction of new dams for hydropower projects. The FERC may issue an exemption at an existing dam or project, or within an existing conduit that was constructed for purposes other than power production.

This NWP is reissued as proposed.

NWP 18. Minor Discharges. The Corps did not propose any changes to this NWP. One commenter expressed support for the reissuance of this NWP with no changes. One commenter said that the limits of this NWP should be increased to 50 cubic yards to match the proposed increase in the cubic yard limit for minor dredging activities authorized by NWP 19. One commenter stated that this NWP should require PCNs for all proposed activities, so that the district engineer can evaluate potential impacts from sediment and other pollutants.

The Corps is retaining the 25-cubic-yard limit for this NWP. Activities authorized by NWP 18 may convert wetlands and other waters to uplands. The Corps is also retaining the 25-cubic-yard limit for NWP 19 as discussed below so NWPs 18 and 19 will remain consistent.

The Corps disagrees that PCNs should be required for all activities authorized by this NWP. This NWP requires PCNs for discharges of dredged or fill material into special aquatic sites and discharges of dredged or fill material into waters of the United States greater than 10 cubic yards below the plane of the ordinary high water mark or the high tide line, and those PCN thresholds are sufficient to help ensure that activities authorized by this NWP result in no more than minimal adverse environmental effects. Division engineers can add regional conditions to this NWP to require PCNs for additional activities authorized by

this NWP, if such regional conditions are necessary to provide district engineer review for proposed activities that may result in more than minimal individual and cumulative adverse environmental effects. The Corps does not have the authority to regulate pollutants other than discharges of dredged or fill material. Discharges of dredged or fill material into waters of the United States authorized by this NWP require water quality certification or waivers to comply with Section 401 of the Clean Water Act. Certifying authorities may issue, deny, or waive water quality certification for discharges authorized by this NWP. When certifying pursuant to section 401, certifying authorities may include conditions to ensure that authorized discharges comply with applicable water quality requirements.

This NWP is reissued as proposed.

NWP 19. Minor Dredging. The Corps proposed to modify this NWP by changing the cubic yard limit from 25 cubic yards to 50 cubic yards. Several commenters expressed opposition to increasing the cubic yard limit for this NWP from 25 cubic yards to 50 cubic yards. Several commenters voiced their support for the proposed change. One commenter recommended increasing the cubic yard limit to 100 cubic yards. A couple of commenters said that the Corps did not provide sufficient explanation as to why increasing the cubic yard limit to 50 cubic yards would ensure that the activities authorized by this NWP will result in no more than minimal adverse environmental effects.

After considering the comments received in response to the 2020 Proposal, the Corps is retaining the 25 cubic yard limit for this NWP. Where the 25-cubic-yard limit would be exceeded, those activities may be authorized under regional general permits or individual permits, including under letters of permission where those tools are available. In geographic areas where minor dredging activities removing up to 25 cubic yards have the potential to result in more than minimal individual and cumulative adverse environmental effects, division engineers can impose regional conditions to reduce the cubic yard limit from 25 yards to a smaller number of cubic yards. Division engineers can also add regional conditions to this NWP to require PCNs for some or all NWP 19 activities to provide district engineers the opportunity to review these minor dredging activities on a case-by-case basis and determine whether they qualify for NWP authorization.

One commenter said that applicants should be required to ensure that toxic substances are not released back into the water column through re-exposure from the dredging activity. One commenter objected to the proposed reissuance of this NWP, stating that the authorized dredging activities will have adverse effects on shellfish beds, infaunal invertebrates, and macroalgal beds, as well as biogenic structures such as shell rubble and large woody debris that provide ecologically valuable habitat, forage areas, or refuge areas for fish, shellfish, or shorebirds.

Minor dredging activities authorized by this NWP may require water quality certification under Section 401 of the Clean Water Act. For a proposed minor dredging activity that may result in a discharge into waters of the United States, the certifying authority may issue, waive, or deny water quality certification. The certifying authority may add conditions to the water quality certification to ensure that the discharge complies with applicable water quality requirements. This NWP does not authorize the dredging or degradation through siltation of coral reefs, sites that support submerged aquatic vegetation, anadromous fish spawning areas, or wetlands. Bivalve molluscs inhabiting shellfish beds may be harvested through dredging activities authorized by other NWPs, such as NWP 4 for fish and wildlife harvesting, enhancement, and attraction devices and activities, or NWP 48 for commercial shellfish mariculture activities. Infaunal invertebrates, beds of macroalgae, and shell rubble areas may be impacted by activities authorized by this NWP, but those impacts are likely to be no more than minimal in the highly dynamic marine and estuarine environments in which those organisms and features are located, where they are subjected to a variety of natural and anthropogenic disturbances, such as disturbances caused by storms, vessels, anchors, and fishing activities. The removal of large woody debris from waterbodies is usually accomplished through snagging rather than dredging.

One commenter said that federal and state natural resource agency coordination should be required for proposed activities that occur in non-tidal waters inhabited by state and/or federally listed threatened and endangered freshwater mussels. A commenter stated that project proponents could piecemeal a number of smaller dredging projects under this NWP to dredge a larger overall area and such activities may negatively affect fish spawning habitat and water quality. One commenter said that this NWP should require the use of silt fences, booms, and bubblers to protect fish, and other natural resources.

Paragraph (c) of general condition 18 requires non-federal permittees to submit a pre-construction notification to the district engineer if any listed species (or species proposed for listing) or designated critical habitat (or critical habitat proposed such designation) might be affected or is in the vicinity of the proposed activity, or if the proposed activity is located in designated critical habitat or critical habitat proposed for such designation. The district engineer will review the proposed activity and if he or she determines that it may affect federally-listed mussel species or other federally-listed endangered or threatened species, the district engineer will initiate ESA Section 7 consultation with the U.S. FWS and/or NMFS as appropriate. Potential impacts to state-listed mussel species are more appropriately addressed through the permittee's compliance with applicable state natural resource or wildlife laws and regulations.

General condition 15 states that the same NWP cannot be used more than once to authorize the same single and complete project. Therefore, this NWP cannot be used multiple times to dredge larger volumes of material from a specific waterbody as part of a larger overall dredging project. The applicant should apply for an individual permit to obtain DA authorization for the larger dredging project unless a different general permit is available to authorize that project. Activities authorized by this NWP can occur in a wide variety of waters, including ocean waters, estuaries, and rivers, and the use of silt fences, booms, and bubblers may be appropriate for some minor dredging activities but not for other minor dredging activities. Therefore, the Corps declines to modify this NWP at a national level to require these mitigation measures for all activities authorized by this NWP.

This NWP is reissued without proposed modification.

NWP 20. Response Operations for Oil or Hazardous Substances. The Corps did not propose any changes to this NWP. One commenter expressed support for the reissuance of this NWP with no changes.

This NWP is reissued as proposed.

NWP 22. Removal of Vessels. The Corps did not propose any changes to this NWP. One commenter recommended changing the text of this NWP to state that land-based alternatives should be considered first for vessel disposal. This commenter also said that intentional ocean disposal of

vessels at sea requires a permit from EPA issued under the Marine, Protection, Research and Sanctuaries Act, and should only be pursued when land-based alternatives are not available.

This NWP authorizes temporary structures in navigable waters of the United States or minor discharges of dredged or fill material into waters of the United States required for the removal of wrecked, abandoned, or disabled vessels, or the removal of man-made obstructions to navigation. The consideration of off-site alternatives is not required for activities authorized by NWPs (see 40 CFR 230.7(b)(1)). If a project proponent intends to dispose of the vessel in ocean waters then a separate authorization from EPA may be required under the Marine, Protection, Research and Sanctuaries Act. Note 1 has been revised to clarify EPA requirements for intentional ocean disposal of vessels under the Marine, Protection, Research and Sanctuaries Act. The project proponent has an independent responsibility to apply to EPA for that authorization.

This NWP is reissued as proposed.

NWP 23. Approved Categorical Exclusions. The Corps did not propose any changes to this NWP. Several commenters requested that the Corps update Regulatory Guidance Letter 05–07 to include all current Federal Transit Administration, Federal Rail Administration, and Federal Highway Administration categorical exclusions so that NWP 23 can be used to authorize regulated activities covered by those categorical exclusions. One commenter stated that this NWP violates the public participation requirements of Section 404(e) of the Clean Water Act because it does not explain how the Chief of Engineers will solicit public comment on categorical exclusions proposed to be added for authorization by this NWP. This commenter also objected to the proposed reissuance of this NWP, stating that it does not authorize categories of activities that are similar in nature, and does not identify which categories of activities are authorized by the NWP. In addition, this commenter said that this NWP authorizes activities that result in more than minimal adverse environmental effects.

As stated in the Note in this NWP, federal agencies may submit requests to Corps Headquarters to seek approval for their categorical exclusions to be authorized by this NWP. The Note also states that, upon receipt of a request from a federal agency to add, modify, or remove categorical exclusions for authorization under this NWP, Corps Headquarters will solicit public comment on the request, and determine which categorical exclusions involving discharges of dredged or fill material into waters of the United States and/or structures or work in navigable waters of the United States will be authorized by the NWP. This NWP provides two opportunities for public participation in the identification of categories of activities authorized by this NWP: (1) The public notice and comment process associated with the proposal to reissue this NWP, and (2) the public notice and comment process associated with the review and approval for specific categorical exclusions to be authorized by this NWP through the issuance of a Regulatory Guidance Letter issued by Corps Headquarters.

This NWP authorizes categories of activities that are similar in nature—that is activities regulated by the Corps that are undertaken, assisted, authorized, regulated, funded, or financed, in whole or in part, by another federal agency or department—where those activities are determined by the federal agency or department to be categorically excluded from the requirement to prepare an environmental impact statement or environmental assessment. The categorical exclusions approved for use with this NWP are identified in a Regulatory Guidance Letter issued by the Corps after a public notice and comment process. Some of these approved categorical exclusions require submittal of PCNs to Corps districts before commencing the authorized activities, so that district engineers can review those activities on a case-by-case basis to ensure that the authorized activities result in no more than minimal individual and cumulative adverse environmental effects. The activities associated with approved categorical exclusions that do not require PCNs were determined by the Corps to result in no more than minimal individual and cumulative adverse environmental effects when the Corps approved those categorical exclusions for use with NWP 23. For those approved categorical exclusions that do not require PCNs, district engineers retain the ability to exercise discretionary authority on a case-by-case basis to modify, suspend, or revoke the NWP authorization if they determine those activities will result in more than minimal adverse environmental effects.

This NWP is reissued as proposed.

NWP 24. Indian Tribe or State Administered Section 404 Programs. The Corps did not propose any changes to this NWP. No comments were received on the proposed reissuance of this NWP. After the comment period for the 2020 Proposal ended on November 16, 2020, the State of Florida was granted approval by the U.S. Environmental Protection Agency to assume the Clean Water Act Section 404 permit program in Florida. Therefore, the Corps has modified Note 1 of this NWP to include Florida in the list of states with approved Clean Water Act Section 404 permit programs. This NWP is reissued with the modification discussed above.

NWP 25. Structural Discharges. The Corps did not propose any changes to this NWP. One commenter objected to the proposed reissuance of this NWP, stating that it contains no limits or other constraints to ensure that it authorizes only activities that have no more than minimal individual and cumulative adverse environmental effects.

This NWP does not have any quantitative limits because it authorizes discharges of dredged or fill material into tightly sealed forms that are used to construct structural components for pile supported structures such as bridges or for mooring cells for general navigation. The losses of waters of the United States authorized by this NWP are limited by the dimensions of the piles, mooring cells, or other structures for general navigation. The dimensions of these tightly sealed forms for supported structures or structures for general navigation will be determined by engineering standards for safe and functional structures, as well as the purpose of the proposed supported structure or navigational structure. These limited size of these structures help ensure that the authorized discharges of dredged or fill material into waters of the United States result in no more than minimal individual and cumulative adverse environmental effects.

In addition, as stated in the text of the NWP, structures in navigable waters of the United States subject to Section 10 of the Rivers and Harbors Act of 1899 require separate authorization because this NWP authorizes only discharges of dredged or fill material into waters of the United States. The section 10 permit process would address the potential impacts of the structure, including the size of the proposed structure, on navigation, the aquatic environment, and the Corps' other public interest review factors.

This NWP is reissued as proposed.

NWP 27. Aquatic Habitat Restoration, Establishment, and Enhancement Activities. The Corps proposed to modify this NWP by changing the second sentence of the second paragraph of this NWP to state that an

ecological reference may be based on the characteristics of one or more intact aquatic habitats or riparian areas. The Corps also proposed to modify this NWP by adding coral restoration or relocation activities to the list of examples of activities authorized by this NWP and stating that PCNs are not required for permittees that propose to conduct coral restoration or relocation activities in accordance with a binding agreement with the NMFS or any of its designated state cooperating agencies. In addition, the Corps proposed to add ''releasing sediment from reservoirs to restore downstream habitat'' to the list of examples of aquatic restoration or enhancement activities that may be authorized by this NWP.

One commenter expressed support for the reissuance of this NWP because it allows for expedited permitting for much needed aquatic habitat restoration and enhancement projects, especially in coastal areas. One commenter stated that broad application of this NWP supports proactive state planning efforts on resiliency and flooding master plans. One commenter recommended revising the text of this NWP to make it clear that it provides approval for restoration projects, particularly those activities that will provide documented net ecological uplifts and have already undergone federal and/or state review through integrated and advance planning activities. One commenter also suggested modifying this NWP to authorize the removal of low-head dams and culverts for stream mitigation credits.

The Corps acknowledges that this NWP provides an expedited authorization process for aquatic habitat restoration, enhancement, and establishment activities that result in net increases in aquatic resource functions and services and have no more than minimal individual and cumulative adverse environmental effects. The aquatic resource restoration, enhancement, and establishment activities authorized by this NWP can be located in coastal areas. The aquatic habitat restoration, enhancement, and establishment activities authorized by this NWP can also provide water retention and storage functions that contribute to ecological services such as natural hazard mitigation, including water storage to reduce flood hazards. The activities authorized by this NWP may have also been reviewed by state agencies and other federal agencies, but review by these agencies is not required before the Corps authorizes these activities under Section 404 of the Clean Water Act and Section 10 of the Rivers and Harbors Act of 1899. The removal of low-head dams to produce stream mitigation credits may be authorized by NWP 53. In the third paragraph of NWP 27, the removal of stream barriers (such as undersized culverts, fords, and grade control structures) is included in the list of examples of activities authorized by this NWP. The removal of undersized or perched culverts may be authorized by this NWP and successful completion of those activities may generate stream compensatory mitigation credits.

A few commenters expressed support for allowing the use of more than one ecological reference site. One commenter said that this NWP should be modified to address inconsistences in triggering mitigation requirements. One commenter said that the word ''delineation'' be replaced with ''description'' in the text of this NWP. Commenter stated preparing an aquatic resources delineation per the Corps' delineation standards and guidelines is a costly and time-consuming component of project planning and does not seem to provide any additional protection to waters and wetlands.

The Corps has adopted the proposed change regarding the use of one or more intact aquatic habitats or riparian areas as an ecological reference site. The sixth paragraph of this NWP states that compensatory mitigation is not required for activities authorized by this NWP because the authorized activities must result in net increases in aquatic resource functions and services. Therefore, there should be no compensatory mitigation requirements for aquatic habitat restoration, enhancement, or establishment activities authorized by this NWP.

The reports required for NWP 27 activities that do not require PCNs must include a delineation of wetlands, streams, and/or other aquatic habitats on the project site. Delineation is necessary to provide district engineers with a sufficient description of the baseline ecological conditions for that site to assist the Corps in determining whether the reported activity is likely to result in net increases in aquatic resource functions and services. A description of aquatic resources on the project site is not sufficient to help district engineers determine whether a proposed activity will satisfy the requirements of this NWP. The project plans for the proposed aquatic habitat restoration, enhancement, or establishment activity, plus the delineation of aquatic resources on the project site, are necessary for making certain determinations. Those determinations are whether net gains in aquatic resource functions and services are likely to occur as a result of the discharges of dredged or fill material into waters of the United States and/or structures or work in navigable waters of the United States, and whether any potential changes to existing aquatic resources on the project site will help ensure that such net gains will occur.

One commenter said that this NWP should be changed to clarify that it authorizes actions by a third-party ecological restoration provider in connection with a compensatory mitigation project, a restoration project, or a resiliency-focused project that generates net ecological uplift. One commenter stated that this NWP should be modified to allow waters and wetland conversions to natural conditions for a different aquatic habitat type if the proposed activity as a whole will result in a net increase in aquatic resource functions and services.

As stated in the ''Note'' in this NWP, this NWP authorizes aquatic habitat restoration, enhancement, and establishment activities that are conducted by third-party ecological restoration providers for the purposes of compensatory mitigation for NWPs and other forms of DA authorization, such as individual permits and regional general permits. This NWP can also be used to authorize aquatic habitat restoration projects that are conducted for the purpose of increasing the functions and services provided by degraded aquatic habitat, but are not being conducted for providing compensatory mitigation for NWPs or other types of DA permits. Resiliency projects may be authorized by this NWP as long as they are aquatic habitat restoration, enhancement, or establishment projects, result in net gains in aquatic resource functions and services and resemble ecological references. Some resiliency projects, such as nature-based solutions that are modified ecosystems designed and constructed to provide ecosystem functions and services (National Academy of Sciences 2019), might not resemble ecological references because they consist of combinations of natural and engineered components. Living shorelines are an example of resiliency projects in coastal areas that do not resemble ecological references because they may include engineered structures such as sills or breakwaters. Living shorelines can be authorized by NWP 54. Green infrastructure projects constructed to manage stormwater, such as rain gardens or constructed wetlands, might not resemble ecological references and may be authorized by NWP 43 or other NWPs, or by individual permits.

The Corps is retaining the current prohibitions on conversions of streams or natural wetlands to other aquatic

habitat types because those conversions typically focus on increasing a specific aquatic resource function or service while resulting in net losses in most of the other ecological functions and services performed by the impacted aquatic habitat type. These converted aquatic habitats may also result in hybrid aquatic habitats that do not resemble ecological references. This NWP also retains the prohibitions on the conversion of tidal waters and tidal wetlands to other aquatic uses, to ensure that activities authorized by NWP 27 result in no more than minimal individual and cumulative adverse environmental effects. Conversions of natural wetlands, streams, and other types of waters to different aquatic habitat types result in artificial conditions, not natural conditions, and project proponents can seek DA authorization for these activities through other means, such as the individual permit process, other NWPs, or if available, regional general permits.

One commenter said that the Corps should issue a separate NWP for voluntary wetland restoration projects to distinguish those projects from development projects. One commenter stated that the text of this NWP should include a definition for voluntary wetland restoration projects that includes restoration projects that occur in altered, degraded, and former wetlands. A commenter said that a new federal process should be established for permitting voluntary wetland restoration projects. One commenter said that to ensure that voluntary wetland restoration projects result in net increases of wetland functions and services, those projects should be prohibited as serving to fulfilling mitigation requirements. One commenter stated that this NWP should clarify that it authorizes permittee-responsible mitigation activities.

This NWP authorizes both voluntary wetland restoration projects and wetland restoration projects that are required by regulatory agencies or other agencies. This NWP does not authorize development activities. Other NWPs, such as NWP 29 (residential developments) and NWP 39 (commercial and institutional developments), may be used to authorize development activities. The Corps declines to add a definition of ''voluntary wetland restoration project,'' because this NWP does not distinguish between voluntary wetland restoration projects and wetland restoration projects that may be conducted for other reasons, such as wetland restoration requirements imposed by other federal, tribal, state, or local government agencies. There is no need to establish a new federal permitting process for voluntary wetland restoration projects because the Corps currently authorizes wetland restoration projects through its permitting authorities under Section 404 of the Clean Water Act and Section 10 of the Rivers and Harbors Act of 1899. While this NWP can be used to authorize discharges of dredged or fill material into waters of the United States and/or structures or work in navigable waters of the United States for wetland restoration projects, those activities can also be authorized by individual permits and regional general permits.

Voluntary wetland restoration projects are conducted by people or organizations for the purpose of increasing wetland acreage and the associated wetland functions and services, or the level of wetland functions and services performed by areas of existing, degraded wetlands. Wetland restoration for compensatory mitigation serves a different purpose, which is to offset losses of wetland functions and services caused by permitted activities. Third-party mitigation providers (*e.g.,* mitigation bank sponsors and in-lieu fee program sponsors) may conduct wetland restoration projects to provide compensatory mitigation for NWPs and other DA permits, or to fulfill other federal, state, or local government mitigation requirements without being driven to do so by regulatory requirements. Both voluntary wetland restoration projects and wetland compensatory mitigation projects are expected to result in net increases in wetland functions and services, which is a basic requirement of this NWP. This NWP can be used to authorize permittee-responsible mitigation projects, including advance permittee-responsible mitigation projects where there is no DA permit to authorize discharges of dredged or fill material into waters of the United States or structures or work in navigable waters of the United States for the advance permittee-responsible mitigation project.

One commenter said that this NWP should be modified to explicitly add the restoration of vegetated and unvegetated intertidal and subtidal areas—including mudflats, sandflats, and submerged aquatic vegetation—to the list of examples of activities authorized by this NWP. Commenter said that the activities authorized by this NWP will alter and destroy open water habitats in tidal estuaries and convert them to types of habitat that were never historically present in those waters. This commenter also stated that the activities authorized by this NWP would make open water sites unusable by fishermen and species that currently rely on those open water habitats. One commenter said that the authorization of structures and fills by this NWP creates overlap between NWP 27 and NWP 54 (living shorelines) and should be revised. One commenter stated that the text of this NWP should be clarified regarding the degradation of downstream waters.

As stated in the first paragraph of this NWP, it authorizes the rehabilitation and enhancement of tidal streams, tidal wetlands, and tidal open waters as long as those activities result in net increases in aquatic resource functions and services. This includes vegetated and unvegetated intertidal areas (*e.g.,* mud flats and sand flats) and vegetated and unvegetated subtidal areas (*e.g.,* submerged aquatic vegetation). Tidal open waters include mud flats and sand flats. Tidal wetlands include submerged aquatic vegetation. The fifth paragraph of this NWP states that it does not authorize activities that convert tidal waters, including tidal wetlands, to other aquatic uses. Therefore, this NWP cannot be used to authorize discharges of dredged or fill material that convert tidal waters into uplands or non-tidal aquatic habitats. In addition, because the text of this NWP states that it authorizes the rehabilitation and enhancement of tidal open waters, it limits the authorized activities to those that improve either the suite of functions or a smaller number of functions performed by tidal waters. It does not authorize activities that degrade or destroy tidal waters, or render them unusable by fishermen. Aquatic habitat restoration and enhancement activities may alter which species use the restored or enhanced site, and which habitat functions support or deter certain species.

Activities authorized by NWP 27 must result in an aquatic habitat that resembles an ''ecological reference,'' consistent with the definition of that term in section F of the NWPs. A living shoreline usually consists of living components (*e.g.,* marsh grasses, oysters) and engineered components (*e.g.,* sills or breakwaters constructed from stone), and may not resemble an ecological reference. There is no overlap between NWP 27 and NWP 54, although tidal wetlands restored or enhanced as a result of the activities authorized by this NWP may help reduce erosion as an ecological service.

Several commenters stated that NWP 27 has PCN thresholds that are inconsistent with, and more stringent than, the PCN thresholds for other NWPs, such as NWP 12 and the two

new NWPs 57 and 58 that were issued in the final rule published in the January 13, 2021, issue of the **Federal Register** (86 FR 2744). Some of these commenters suggested that this NWP should be modified to require PCNs for proposed discharges of dredged or fill material into non-wetland special aquatic sites or if the proposed activity results in loss of greater than 1/10-acre of wetland. One commenter stated support of the PCN notification exemption to continue to allow statewide aquatic habitat restoration and enhancement activities to be conducted in an efficient and timely manner. One commenter said that in order to reduce unnecessary delays and expenses from the PCN process, this NWP should be modified by removing the exception from the requirement to submit PCNs for activities on non-federal public lands and private lands conducted under agreements between the landowner and federal agencies or their designated state cooperating agencies.

The PCN thresholds for this NWP are no more stringent that the PCN thresholds for many other NWPs. All activities authorized by this NWP require some form of advance notification to district engineers before commencing authorized activities, to provide district engineers with the opportunity to take action on those proposed activities that do not comply with the requirements of the NWP, such as activities that are not expected to result in net gains in aquatic resource functions and services or activities that are not likely to resemble ecological references. The advance notification takes the form of either: (1) Pre-construction, or (2) reporting. The activities identified in the ''Notification'' paragraph require PCNs and reports are required for the activities identified in the ''Reporting'' paragraph. Most of the NWPs require PCNs for all authorized activities, or for a subset of authorized activities.

The suggested PCN thresholds for discharges of dredged or fill material into non-wetland special aquatic sites or for losses of greater than 1/10-acre of wetland are not appropriate for an NWP that authorizes discharges of dredged or fill material or structures or work into all types of waters of the United States. Wetlands are a subset of jurisdictional waters in which this NWP can be used to authorize regulated activities associated with aquatic habitat restoration, enhancement, and establishment. This NWP authorizes activities in tidal and non-tidal wetlands, rivers and streams, lakes, estuaries, and ocean waters. Some form of case-by-case review is needed for all authorized activities to ensure their compliance with the NWP and that they will result in no more than minimal individual and cumulative adverse environmental effects.

This NWP does not have an acreage or other quantitative limits. Instead of a quantitative limit, this NWP requires that aquatic habitat restoration, enhancement, and establishment activities result in net increases in aquatic resource functions and services and resemble ecological references. Aquatic habitat restoration, enhancement, and establishment activities can occur over large or small areas, and the PCN and reporting requirements facilitate the expedited review process for activities that provide benefits for the aquatic environment, as well as ecological services for people. The reporting requirement was established for certain NWP 27 activities on non-federal public lands and private lands to reduce costs associated with preparing PCNs, while providing district engineers with the opportunity to review proposed activities that do not require PCNs. The reporting requirement provides district engineers with the opportunity to take action if they determine that a proposed activity does not qualify for NWP 27 authorization because it is not an aquatic habitat restoration, enhancement, or establishment activity; it is not likely to result in net gains in aquatic resource functions and services; or it does not resemble an ecological reference.

Several commenters expressed support for adding coral restoration activities to the list of examples of activities that may be authorized by NWP 27. One commenter stated that authorizing coral restoration activities under this NWP would streamline and simplify restoration activities and reduce burdens on the local agencies.

The Corps has added coral restoration activities and coral relocation activities to the list of examples of activities authorized by this NWP when those activities require DA authorization under Section 10 of the Rivers and Harbors Act of 1899 and/or Section 404 of the Clean Water Act.

Many commenters stated opposition to the proposed inclusion of reservoir sediment releases as an example of an activity authorized by NWP 27 while many commenters expressed support for the proposed inclusion of that activity as an example of activities authorized by this NWP. A few commenters stated that controlled sediment releases can benefit downstream river and stream beds and embankments. One commenter asserted that these activities should require individual permits. One commenter suggested rewording the proposed modification to the following: ''reservoir sediment management to provide continuity in sediment transport through reservoirs.''

The Corps is adding ''releases of sediment from reservoirs to maintain sediment transport continuity to restore downstream habitats'' to the list of examples of activities authorized by this NWP instead of the proposed text of ''releasing sediment from reservoirs to restore downstream habitat.'' These activities can be conducted in a manner that improves the functions and services performed by downstream river and stream habitats and results in no more than minimal individual and cumulative adverse environmental effects. The revised text is intended to emphasize the notion of rehabilitating downstream habitats and improving the functions and services performed by those habitats by maintaining continuity of sediment transport through reservoirs rather than emphasizing reservoir management activities. Sediment releases from reservoirs must have the purpose of maintaining sediment transport through rivers that sustains or improves downstream habitat that is adversely affected by the reservoir because that reservoir disrupts normal sediment transport processes in the river. The Corps declines to revise the text to refer to reservoir sediment management activities because the modification of this NWP addresses only one approach to reservoir sediment management.

The movement of sediment via flowing water through watersheds and river and stream networks is a natural watershed process (Black 1997). Reservoirs trap sediment and disrupt the continuity of sediment transport though the river network in a watershed, which reduces the amount of sediment transported downstream that helps maintain river channel form as well as adjacent riparian areas and floodplains (Kondolf et al. 2014). Periodic releases of sediment stored in reservoirs can help maintain the continuity of sediment transport in riverine systems and help sustain or enhance downstream riverine and riparian habitats, including floodplains. In coastal areas, periodic releases of sediment from reservoirs can provide sediment that helps sustain coastal wetlands and unvegetated coastal habitats (Kondolf et al. 2014). Those sediments can accrete in coastal wetlands and help those wetlands adjust to sea level rise. The activities authorized by this NWP require either PCNs or reports to district engineers, so

it is not necessary to add a PCN requirement specific to releases of sediment from reservoirs to maintain sediment transport continuity in riverine systems to restore or enhance downstream habitats. District engineers will review these proposed activities through either PCNs or reporting documentation submitted by project proponents to Corps district offices.

Releases of sediment from reservoirs may or may not require DA authorization, depending on how those sediment releases are conducted. Guidance is provided in Regulatory Guidance Letter (RGL) 05–04: ''Guidance on the Discharge of Sediments From or Through a Dam and the Breaching of Dams, for Purposes of Section 404 of the Clean Water Act and Section 10 of the Rivers and Harbors Act of 1899.'' The RGL explains the circumstances in which sediment releases from reservoir do not require DA authorization, and how reservoir sediment releases can be conducted without the need to obtain Clean Water Act Section 404 authorization from the Corps. In general, releases of sediments that are incidental to normal reservoir operations—such as releases of water through the dam to restore reservoir capacity during events like spring run-off, flooding, or storms—are considered de minimis discharges of dredged material. They do not require DA authorization under section 404 so long as the sediment loads of waters released from reservoirs are consistent with the sediment loads entering the reservoir from the upstream waters. The modification of this NWP clarifies that this NWP can be used to provide DA authorization under Section 404 of the Clean Water Act and Section 10 of the Rivers and Harbors Act for sediment releases from reservoirs that require such authorization, as long as those sediment releases rehabilitate downstream habitats and result in net gains in aquatic resource functions and services.

Several commenters stated that sediment releases from reservoirs authorized by this NWP should have quantitative limits to ensure that no more than minimal adverse impacts occur as a result of these activities. One commenter said that the text of this NWP should clarify that sediment releases from reservoirs must be linked to a clear restoration action or plan and should not be authorized by this NWP solely for the purpose of reservoir management or dam maintenance. Many commenters stated that PCNs should be required for all sediment releases authorized by this NWP. Several commenters objected to the proposed modification, stating that sediment release activities under NWP 27 should require PCNs when dam removal projects would result in large amounts of sediments being released. One commenter said that a PCN threshold should be added to this NWP to address discharges associated with sediment releases and the frequency of those sediment releases, to ensure that those activities result in no more than minimal adverse environmental effects.

The Corps does not agree that there should be quantitative limits for reservoir sediment releases authorized by this NWP because of the variability in hydrology and sediment transport in rivers and streams across the country and the variability in reservoir characteristics, such as their dimensions, how they are operated, and the hydrologic and sediment regimes of the watershed in which a reservoir is located. In addition, the appropriate amount of sediment that may be released from a reservoir to maintain continuity of sediment transport to restore downstream habitats is affected by a number of factors, which makes it infeasible to establish a national quantitative limit for these activities. Such factors include water and sediment inputs to the river, including upstream, lateral, and downstream inputs; valley geometry, substrate, and vegetation; river geometry, including the cross sectional geometry, planform, and gradient; and the disturbance regime of the river (Wohl et al. 2015). These factors vary considerably among rivers across the United States. Therefore, the appropriate amount of sediment to be released from reservoirs, as well as the timing of those releases, to provide sediment transport continuity and rehabilitate downstream habitats needs to be determined on a case-by-case basis.

Activities authorized by NWP 27, including wetland and stream restoration and enhancement activities, do not require formal restoration plans, although a project proponent may provide restoration plans with the PCN or report if she or he believes that information would help the district engineer determine whether the proposed activity is authorized by this NWP. The Corps does not believe it is necessary to require more information for proposed releases of sediment from reservoirs than it requires for other aquatic habitat restoration, enhancement, or establishment activities authorized by this NWP. Wetland and stream restoration activities can involve substantial amounts of earth moving and sediment releases, and the Corps believes that proposed releases of sediment from reservoirs do not require a higher information standard than wetland and stream restoration activities. The sediment releases from reservoirs to rehabilitate downstream habitats do not require a formal restoration plan, but the reservoir operator may develop an operations plan that establishes protocols for sediment releases that are intended to maintain sediment transport continuity to restore downstream habitats. The project proponent can provide a copy of that plan with the PCN or report.

To be authorized by this NWP, the sediment releases from reservoirs must result in net gains in aquatic habitat functions and services. This NWP does not authorize sediment releases that are conducted primarily for the purpose of reservoir management or maintenance. The primary purpose of the authorized activity must be to restore downstream habitats. However, controlled releases of sediment from reservoirs to maintain sediment transport continuity to restore or enhance downstream habitats may have a secondary benefit of prolonging the operational life of reservoirs and reducing the need to construct additional reservoirs in a region (Kondolf et al. 2014). This NWP does not authorize releases of large amounts of sediment from reservoirs that would adversely affect downstream habitats and result in net losses, rather than net gains, in aquatic resource functions and services.

Several commenters said that the text of this NWP should clarify whether the sediment releases from reservoirs are one-time activities or they can be conducted on a recurring, routine basis. One commenter said that PCNs for proposed sediment releases from reservoirs should indicate whether the proposed release is part of a single event or proposed as a routine management technique and should include a plan describing the amount, frequency, timing, and duration of sediment to be released. A few commenters support adding releases of sediment from reservoirs into downstream habitats to the examples in NWP 27, but said that sediment releases should have established criteria as determined by state resource managers to maintain balanced sediment levels within individual watersheds.

The timing and frequency of sediment releases from reservoirs to restore downstream habitats are likely to differ because of the variability in climate, watersheds, and rivers across the country, and the variability in water and sediment regimes in rivers. Sediment releases from reservoirs that trigger a

requirement for DA authorization under Section 404 of the Clean Water Act and/or Section 10 of the Rivers and Harbors Act of 1899 may occur during multiple times during the 5-year period this NWP is in effect. This NWP includes a number of examples of authorized activities that may occur more than once during the 5-year period the NWP is in effect, such as the removal of accumulated sediments from waterbodies, shellfish seeding activities, plowing or discing activities for seeding and planting wetland species, and mechanized land clearing to remove non-native invasive, exotic, or nuisance vegetation. If the project proponent anticipates conducting multiple sediment releases during the period this NWP authorization is in effect, in the PCN or report for the proposed activity he or she should provide information on the anticipated number of releases during that time. If the proposed activity requires a PCN, the description of the proposed activity required by paragraph (b)(4)(i) of general condition 32 should including the number of anticipated sediment releases from the reservoir and their timing. Sediment transport in rivers typically occurs in a non-linear, episodic manner (Wohl et al. 2015), and releasing sediments in smaller pulses may more closely mimic non-linear, episodic natural sediment transport processes. This NWP does not authorize large sediment releases that will cause losses of aquatic resource functions and services.

The Corps does not agree that there should be coordination of proposed activities between district engineers and state resource managers. None of the other aquatic habitat restoration, enhancement, and establishment activities authorized by this NWP require coordination between district engineers and state resource managers. Therefore, releases of sediment to restore or enhance downstream habitat should not be subject to a coordination requirement between district engineers and state resource managers. However, district engineers have the discretion to coordinate proposed NWP 27 activities requiring DA authorization with other federal, tribal, state, or local resource agencies on a case-by-case basis, within the timeframes for reviewing PCNs (generally 45 days) and reports (30 days), if they want assistance with their evaluations of those PCNs and reports.

A few commenters stated that sediment releases authorized by this NWP should be clearly linked to a restoration plan and not be solely for the purpose of reservoir or dam maintenance. Several commenters stated that PCNs for proposed sediment releases from reservoirs should include study results that evaluated and addressed the volume of sediment to be released, sediment size and distribution, reach conditions, downstream habitat and aquatic species impacts, and the time of year for releases. Another commenter stated that PCNs for sediment release activities authorized by this NWP should include the plan used for sediment releases and the benefits of each activity must be clarified regarding the resulting changes on hydrology, geomorphology, and habitat, as well as watershed stability.

Aquatic habitat restoration, enhancement, and establishment activities authorized by NWP 27 do not require comprehensive restoration plans. Releases of sediment from reservoirs to maintain sediment transport continuity to restore downstream habitats that require DA authorization will require either PCNs or reporting to district engineers. The Corps does not agree that it is necessary to establish information requirements for releases of sediment from reservoirs that differ from the information requirements for the wide variety of other aquatic habitat restoration, enhancement, or establishment activities authorized by this NWP. The Corps is applying the same PCN information requirements for proposed sediment releases from reservoirs that it requires for all other aquatic habitat restoration, enhancement, and establishment activities authorized by this NWP. Those other aquatic habitat restoration, enhancement, and establishment activities, including wetland and stream restoration activities, can involve substantial amounts of discharges of dredged or fill material into waters of the United States and other regulated activities to restore, enhance, or establish aquatic habitats so that they provide net increases in aquatic resource functions and services after completion of the authorized activities.

For those activities that require PCNs, paragraph (b)(4)(i) of general condition 32 requires the following: A description of the proposed activity; the activity's purpose; direct and indirect adverse environmental effects the activity would cause, including the anticipated amount of loss of wetlands, other special aquatic sites, and other waters expected to result from the NWP activity; and a description of any proposed mitigation measures intended to reduce the adverse environmental effects caused by the proposed activity. The amount and type of information to be provided in the description of the proposed activity in the PCN should be appropriate to the type of aquatic habitat restoration, enhancement, or establishment activity the project proponent wants to conduct under the NWP 27 authorization. For example, for proposed sediment releases to restore downstream aquatic habitats, in the description of the proposed activity the project proponent should describe the amount, frequency, timing, and duration of sediment to be released from the reservoir. A formal study is not required for a complete PCN. The project description should be in sufficient detail to provide the district engineer with enough information to determine whether the proposed activity will result in a net increase in aquatic resource functions and services.

For releases of sediment from reservoirs that may be authorized by this NWP, the PCN should also describe any mitigation measures the project proponent intends to implement to reduce adverse environmental effects and ensure that the authorized activity results in net gains in aquatic resource functions and services. Mitigation measures may include releasing sediment in pulses during periods of sufficient water flow so that the released sediments restore or enhance, rather than degrade, downstream habitats. Releases of sediment from reservoirs to maintain continuity of sediment transport and restore downstream habitats can have a secondary benefit of helping maintain the water storage capacity of reservoirs. However, if the PCN or report states that primary purpose of the sediment releases are for reservoir maintenance, then the district engineer should notify the project proponent that the proposed activity is not authorized by NWP 27, and that another type of DA authorization will be needed for the proposed reservoir or dam maintenance activities.

The sediment releases from reservoirs authorized by this NWP are not likely to result in substantial changes in hydrology, geomorphology, aquatic habitat, or watershed stability because they are intended to maintain continuity in sediment transport to restore or enhance downstream habitats that have been adversely affected by the disruption in sediment transport processes caused by the construction of a reservoir. The activities authorized by this NWP must result in net gains in aquatic resource functions and services. These activities are likely to improve watershed functioning and the sustainability of aquatic habitats within the watershed to some degree by maintaining the continuity of sediment transport in rivers within the watershed.

One commenter stated additional clarification on the definition for the

term ''release'' is needed to encourage natural sediment transport downstream if that is the intent of the proposed change to this NWP. One commenter expressed concern with authorizing sediment releases from reservoirs under this NWP because of uncertainty of the objectives and nature of potential sediment releases. One commenter said that releasing sediment from reservoirs to restore downstream habitat is not suitable for NWP authorization because while it can improve habitat, it can also result in adverse effects on wetlands and riparian areas.

The term ''release'' applies to discharges of dredged or fill material regulated under Section 404 of the Clean Water Act and ''work'' regulated under Section 10 of the Rivers and Harbors Act of 1899 because those are the types of activities authorized by this NWP under the permitting authorities for NWP 27. There are circumstances where releases of sediment from reservoirs do not require DA authorization (see Regulatory Guidance Letter 05–04). The intent of adding ''releases of sediment from reservoirs to maintain sediment transport continuity to restore downstream habitats'' to the list of examples of activities authorized by this NWP is to clarify that this NWP can be used to authorize sediment releases from reservoirs that require DA authorization as long as those activities result in net gains in aquatic resource functions and services and have no more than minimal adverse environmental effects. The third paragraph of this NWP is a list of examples of aquatic habitat restoration, enhancement, and establishment activities that may be authorized by this NWP when those activities require DA authorization. This addition to the list of examples of activities authorized by this NWP is highly specific; it is limited to sediment releases from reservoirs that maintain sediment transport continuity to restore downstream habitat. It does not cover sediment releases from reservoirs for other purposes, such as maintaining the designed water storage capacity of the reservoir. The objective of this addition to the list of examples of activities authorized by this NWP is to provide sediment for downstream habitats that have been adversely affected by the disruption of sediment transport caused by the dam that created the reservoir, so that continuity of sediment transport is maintained to a degree that helps sustain or improve the structure, functions, and dynamics of downstream riverine and riparian habitats, and in coastal areas, downstream coastal habitats.

Sediment releases from reservoirs can be conducted in a manner that does not require DA authorization. Sediment releases from reservoirs can also be conducted in a manner so that they result in no more than minimal individual and cumulative adverse environmental effects. This NWP requires that releases of sediment from reservoirs that require DA authorization result in net gains in aquatic resource functions and services. Sediment releases from reservoirs that require DA authorization but do not result in net gains in aquatic resource functions and services are not authorized by this NWP. The construction of reservoirs disrupts sediment transport to downstream habitats, including wetlands and riparian areas. When sediment transport processes are disrupted by the construction of a dam across a river, downstream riverine wetlands and riparian areas may erode when sediment supplies from upstream waters diminish as sediment is trapped by the reservoir. Coastal wetlands also require periodic inputs of sediment to sustain their structure and function, and sediment releases from reservoirs in coastal areas can help sustain these wetlands (Kondolf et al. 2014). While this NWP may authorize the removal of small water control structures, it does not authorize the removal of large dams. Low-head dam removals may be authorized by NWP 53.

Several commenters stated that the timing, location, and magnitude of sediment releases are crucial factors, as they could be beneficial for some species that require turbidity for spawning, or harmful for species that require clean substrate for nest building. One commenter said that the Corps' decision document for this NWP should provide further clarification of the positive and negative impacts on the aquatic environment downstream from sediment releases and that the NWP should provide a mechanism that will carefully consider these potential impacts and offer practices aimed to reduce negative impacts. One commenter stated that the NWPs are designed for minor discharges with no more than minimal adverse environmental impacts and that individual permits should be required for discharges of sediment for habitat improvement. One commenter said that large amounts of sediments being released downstream should require full evaluation of best management options.

The Corps agrees that the timing, location, and magnitude of sediment releases are crucial factors, and that these activities need to be carefully planned and implemented to ensure that the sediment releases from reservoirs result in net increases in aquatic resource functions and services. The degrees to which some species may benefit from the sediment released from reservoirs and other species may be adversely affected weighs into the determination as to whether the sediment releases result in net gains in aquatic resource functions and services. As with many aquatic habitat restoration, enhancement, and establishment activities, there may be short-term, temporary adverse effects while authorized activities such as discharges of dredged or fill material into waters of the United States are conducted. But over the long-term, as the aquatic habitat responds to the restoration, enhancement, or establishment activities through ecosystem development processes, there should be more permanent, sustainable gains in aquatic habitat functions and services. The Corps has revised its national decision document for this NWP to provide additional discussion of the positive and negative impacts of releases of sediment from reservoirs to maintain sediment transport continuity to rehabilitate downstream aquatic habitats.

If the district engineer reviews the PCN or report and determines the proposed activity may affect listed species or designated critical habitats, the district engineer will conduct ESA Section 7 consultation with the U.S. FWS and/or NMFS as appropriate, unless another federal agency has conducted ESA Section 7 consultation for the proposed activity. The information requirements for these activities are similar to the information requirements for other aquatic habitat restoration, enhancement, and establishment activities authorized by this NWP, and project proponents can provide additional information voluntarily if they think that additional information will help with receiving an NWP verification letter from the district engineer.

When evaluating PCNs for proposed NWP 27 activities, district engineers will consider the 10 criteria in paragraph 2 of section D, District Engineer's Decision to determine whether a proposed activity will result in no more than minimal individual and cumulative adverse environmental effects. Aquatic habitat restoration, enhancement, and establishment activities can vary substantially in size, and in the amount of dredged or fill material that is discharged into waters of the United States to conduct those activities. For aquatic habitat restoration, enhancement, and

establishment projects, the quantity of discharges of dredged or fill material into waters of the United States is not indicative of whether the completed activity will result in net gains in aquatic habitat functions and services. It is the longer-term outcomes of the aquatic habitat restoration, enhancement, or establishment activities that determine whether net gains in aquatic resource functions and services occur after the temporary impacts associated with the permitted activities are supplanted by the ecosystem development processes that occur over time to produce gains in aquatic resource functions and services. These concepts apply to releases of sediment from reservoirs to maintain sediment transport continuity to restore downstream habitats.

Many commenters expressed concern with possible levels of pollutants and water quality impairments from sediment releases. One commenter stated that dam removal projects require sediment contaminant testing to ensure sediment contaminants to be released downstream would not negatively impact the environment, and that this NWP should have a similar requirement for sediment releases from reservoirs. One commenter stated that release of sediments from reservoirs as part of a restoration activity should not contain actionable levels of pollutants such as nitrates, phosphorus, metals, or pesticides. Many commenters said that PCNs for proposed releases of sediment from reservoirs should require sediment analysis to determine contaminant levels. One commenter said that sediment load and the concentrations of any contaminants relative to background levels are key parameters for determining downstream environmental impacts of these activities. Many commenters said that there is potential for contaminants and pollutants that have accumulated in reservoir sediments to be released which may cause significant ecosystem impacts downstream. A few commenters stated that sediment releases from reservoirs would result in water quality violations and disperse contaminated sediments.

Dam removal projects do not always require sediment testing. The need for sediment testing for sediments to be released via dam removal project is determined on a case-by-case basis by applying the criteria at 40 CFR 230.60. The same approach applies to releases of sediment from reservoirs to maintain sediment transport continuity to restore downstream habitats. In addition, sediment releases from reservoirs authorized by this NWP may require water quality certification under Section 401 of the Clean Water Act. The applicable certifying authority determines whether a discharge may occur, and if the certifying authority determines that a discharge into waters of the United States may occur it notifies the project proponent that water quality certification or waiver is required before conducting the proposed discharge.

Decisions to require testing of sediments released from reservoirs are more appropriately made by the agencies responsible for making water quality certification decisions under Section 401 of the Clean Water Act. If the proposed release of sediment from a reservoir requires DA authorization, the district engineer should defer to the applicable certifying authority regarding whether sediment testing is necessary to ensure compliance with applicable water quality requirements. If a release of sediments from a reservoir will result in a regulated discharge of dredged or fill material, the district engineer has the discretion to determine that there is a need to test sediment that might be stored in the reservoir for contaminants, based on a ''reason to believe'' approach similar to the EPA's inland testing manual for dredged material.

One commenter expressed concern for authorizing sediment releases under an NWP because there is little opportunity for coordination with natural resource agencies. A few commenters said that the Corps should develop appropriate general and/or regional conditions for reservoir sediment releases through coordination with natural resource agencies and reservoir operators. One commenter stated that the Corps should require project proponents proposing sediment releases from reservoirs to notify downstream drinking water utilities of potential sediment releases when necessary to benefit downstream habitat. One commenter said that PCNs for proposed sediment releases from reservoirs should require consultation with state resource agencies to ensure potential sediment contamination and changes in dissolved oxygen levels are considered because suspended and embedded sediment has been shown to affect aquatic species, such as fish, through direct physiological effects, decreased water clarity, or sediment deposition.

The Corps does not believe it is necessary to require agency coordination for PCNs or reports submitted to district engineers for releases of sediment from reservoirs to maintain the continuity of sediment transport in riverine systems, when those activities are authorized by this NWP. District engineers have the discretion to coordinate PCNs and reports with their counterparts at federal, tribal, state, or local resource agencies. Sediment transport in rivers and streams is a natural process, with a suspended load conveying finer sediment in the water column and a bed load conveying coarser sediment along the river or stream bed. Therefore, the Corps does not believe that it is necessary to notify downstream drinking water utilities of proposed releases of sediment from reservoirs. Potential concerns about sediment contamination and changes in dissolved oxygen levels are more appropriately addressed by certifying authorities through the Clean Water Act Section 401 water quality certification process. Sediment transport is a natural river function, and fish that live in rivers are adapted to cope with suspended sediments and sediments on the river bed. The activities authorized by this NWP must result in net gains in aquatic resource functions and services and result in no more than minimal individual and cumulative adverse environmental effects. District engineers will review PCNs and reports for these proposed activities, and if they determine that adverse effects to fish and other aquatic organisms will be more than minimal after considering mitigation proposed by project proponents, they will exercise discretionary authority and require individual permits for these activities.

One commenter recommended modifying this NWP to allow longer reaches of stream be allowed to be temporarily impacted without need for a permit to help to facilitate more streambank stabilization and restoration activities, because of the high costs for designing, engineering, and permitting these activities. This commenter said that these administrative costs often exceed the actual cost of implementing the beneficial improvement work. One commenter said that the Corps must assess the potential for NWP 27 activities to affect ESA-listed species, and that potential impacts from those activities must be analyzed through programmatic ESA Section 7 consultations.

This NWP has no quantitative limits, so there are no limits on the amount of stream bed that can be restored or enhanced by activities authorized by this NWP. There are no exemptions from Clean Water Act Section 404 permitting requirements for stream restoration activities. Paragraph (c) of general condition 18, endangered species, requires non-federal permittees to submit a pre-construction notification

to the district engineer if any listed species (or species proposed for listing) or designated critical habitat (or critical habitat proposed such designation) might be affected or is in the vicinity of the activity, or if the activity is located in designated critical habitat or critical habitat proposed for such designation. District engineers will review those PCNs and determine whether the proposed activity may affect listed species or designated critical habitat. If the district engineer determines a proposed activity may affect ESA-listed species or designated critical habitat, then she or he will conduct ESA Section 7 consultation with the U.S. FWS and/or NMFS as appropriate. Compliance with ESA Section 7 may be achieved through activity-specific formal or informal ESA Section 7 consultations or formal or informal regional programmatic ESA Section 7 consultations.

One commenter stated that the scope of projects authorized by NWP 27 should be broadened to expedite the review and permitting process to help support the growing ecological restoration industry. One commenter requested that Corps be required to issue an NWP 27 verification concurrent with the execution of a mitigation banking instrument in states where a state has assumed the responsibilities for permitting discharges of dredged or fill material into waters of the United States.

This NWP authorizes a wide variety of aquatic habitat restoration, enhancement, and establishment activities. Those activities can be conducted by the ecological restoration industry, government agencies, non-governmental organizations, private individuals, and other entities. If a state has assumed the responsibilities for implementing the Clean Water Act Section 404 permit program, this NWP likely cannot be used to authorize discharges of dredged or fill material into waters of the United States in waters that have been assumed by that state. A state permit would be required to authorize those discharges of dredged or fill material into waters of the United States.

This NWP is reissued, with the modifications discussed above.

NWP 28. Modifications of Existing Marinas. The Corps did not propose any changes to this NWP. No comments were received on the proposed reissuance of this NWP. This NWP is reissued as proposed.

NWP 30. Moist Soil Management for Wildlife. The Corps did not propose any changes to this NWP. One commenter objected to the proposed reissuance of this NWP because it does not require PCNs for proposed activities. This commenter said that not requiring PCNs for the authorized activities prevents the Corps from tracking the use of this NWP and adding conditions to the authorization.

The purpose of this NWP is to authorize discharges of dredged or fill material into non-tidal waters of the United States to manage wildlife habitat and to provide feeding areas for wildlife. The activities authorized by this NWP cannot cause net losses of aquatic resource functions and services, and it does not authorize the conversion of wetlands or streams to other types of habitat. Since this activities authorized by this NWP help sustain wildlife and cannot result in net losses of aquatic resource functions and services, the Corps does not believe it is necessary to require PCNs for authorized activities. In geographic areas where division engineers have concerns about the potential uses of this NWP, they can add regional conditions to require PCNs for some or all activities authorized by this NWP.

This NWP is reissued as proposed.

NWP 31. Maintenance of Existing Flood Control Facilities. The Corps did not propose any changes to this NWP. A few commenters requested that the Corps not reissue this NWP because they said it authorizes activities that cause more than minimal individual and cumulative adverse environmental effects. A few commenters said that the Corps should impose quantitative limits on this NWP. One commenter stated that relatively small acreage losses authorized by this NWP can cause significant impacts. A few commenters said that the Corps should restrict this NWP so that it authorizes activities that are similar in nature.

This NWP authorizes the maintenance of existing flood control facilities, as long as those activities are conducted within the maintenance baseline established for each flood control facilities. While this NWP does not have a quantitative limit, maintenance activities that require DA authorization are limited to the maintenance baseline that is approved by the district engineer for each existing flood control facility. This NWP does not authorize any expansion or new construction for existing flood control facilities. The existing flood control facilities covered by this NWP were either previously authorized by a Corps permit after the Corps conducted an environmental review (if a Corps permit was required for the original construction of the flood control facility), or constructed by the Corps after completing an environmental review process similar to the Corps' permit review process.

Flood control facilities are located in dynamic environments and require periodic maintenance to sustain their intended flood risk management functions. Aquatic resources located in the existing flood control facilities covered by this NWP provide ecological functions and services, and while periodic maintenance activities can disrupt those functions and services to some degree for a period of time, those aquatic resources usually recover their ability to perform those ecological functions and services. Since this NWP authorizes only maintenance activities, and the aquatic resources in these existing facilities usually recover after disturbances caused by periodic maintenance activities, the Corps believes the activities authorized by this NWP result in no more than minimal adverse environmental effects. Significant impacts are unlikely to occur as a result of these recurring maintenance activities because of the ecological recovery that occurs between each maintenance activity. That ecological recovery likely is the reason why recurring maintenance is needed, because the recovery of biotic and abiotic components within an existing flood control facility, such as vegetation and sediment, may be diminishing the capacity of the flood control facility to perform its intended flood control functions. The activities authorized by this NWP are similar in nature because the NWP is limited to maintenance of existing flood control facilities, within the constraints of a maintenance baseline approved by the district engineer.

Several commenters said that the activities authorized by this NWP can cause adverse impacts to natural and beneficial floodplain functions, including adjacent and downstream impacts of floodwaters on communities and properties. One commenter stated that this NWP inhibits comprehensive basin-wide flood risk management planning and restoration approaches that will help to safeguard communities and protect the nation's natural defenses.

The activities authorized by this NWP are limited to maintenance of existing flood control facilities within a maintenance baseline established by the district engineer. Therefore, the activities authorized by this NWP are unlikely to adversely affect natural floodplain functions because those natural floodplain functions were previously altered by the original construction of the flood control facility. Adverse effects to natural and beneficial

floodplain functions were initially addressed through the authorization process when the flood control facility was originally constructed if the construction of the flood control facility required authorization under Section 404 of the Clean Water Act and/or Section 10 of the Rivers and Harbors Act of 1899 or through the process for approving federal water resource development projects. Maintenance of these existing flood control facilities is necessary to ensure that these facilities continue to provide their intended flood risk management objectives and continue to protect local residences, business, and others from floods. Since this NWP authorizes only maintenance activities, it does not affect efforts to undertake comprehensive, watershed-based flood risk management planning and restoration activities. Watershed-based flood risk management planning and restoration activities can be conducted through other mechanisms, such as cooperative efforts between federal, tribal, state, and local government agencies and interested stakeholders, regardless of whether the Corps reissues this NWP.

Several commenters stated that mitigation should not be limited to one-time-only because maintenance activities could be carried out on multiple occasions and each maintenance activity can cause adverse impacts. One commenter said that the one-time mitigation limit could lead to significant harm to the environment.

This NWP authorizes only maintenance activities for existing flood control facilities that were previously authorized, or did not require DA authorization at the time they were originally constructed. Mitigation, including compensatory mitigation, may have been required for the original construction of the flood control facility. Mitigation may also be required for the original approval of the maintenance baseline by the district engineer. Subsequent recurring maintenance activities to return the existing flood control facility to the maintenance baseline should not require mitigation because those maintenance activities generally have temporary impacts.

The aquatic resources within these existing flood control facilities are likely to recover their ability to perform ecological functions and services after each maintenance activity is conducted to return the flood control to the maintenance baseline established by the district engineer. The one-time maintenance limit recognizes the temporary nature of the impacts to waters of the United States that typically occur as a result of these recurring maintenance activities, including the recovery of aquatic resources that usually occurs between those recurring maintenance activities. The recovery of those aquatic resources generally occurs through natural processes, such as sediment transport and deposition in a waterbody within the existing flood control facility and the re-establishment and growth of plants after vegetation is removed from waterbody or lands next to the waterbody.

A few commenters said that vegetation removal should be addressed by a regional approach based on science and authorized through the individual permit process, with state and federal interagency consultation. One commenter stated that the research points to multiple benefits of vegetation on levees. One commenter said that the Corps' one-size-fits all approach to removal of levee vegetation is opposed by a broad array of states, scientists, members of Congress, and members of the public.

This NWP authorizes discharges of dredge or fill material into waters of the United States and/or work in navigable waters of the United States to return an existing flood control facility to its maintenance baseline so that it can continue to perform its intended flood control functions. A maintenance baseline is established for each existing flood control facility regardless of whether this NWP might be used, and restoring the flood control facility to its maintenance baseline may require the removal of vegetation. Interagency consultation is not required for the activities authorized by this NWP because it is a maintenance activity, and in most cases these maintenance activities must take place on a recurring basis to ensure that the existing flood control facility continues to perform its intended flood control functions and protect the people and property served by that flood control facility. The presence or absence of vegetation within the existing flood control facilities may be addressed through the maintenance baseline. This NWP does not impose any specific requirements regarding vegetation on levees, and it does not prescribe any approach to managing (or not managing) levee vegetation. Whether or not vegetation is allowed to continue to exist on levees or needs to be removed to ensure the structural integrity and continuing functioning of the levee is dependent on the maintenance baseline approved for the flood control facility, as well as any discretion the entity responsible for maintaining the existing flood control facility may have regarding vegetation in that facility.

One commenter stated that it is not possible to determine the full extent of the significance of the impacts caused by activities authorized by this NWP because the draft decision document provides no information on the types of waters affected, the location of those waters, or other activities that have or are likely to affect those waters. One commenter stated that the draft decision document for this NWP demonstrates that the activities authorized by this result in more than minimal impacts, because approximately 225 activities impacted 500 acres of jurisdictional waters and wetlands. One commenter said that the decision document for this NWP should include impacts quantified in linear feet.

This NWP can be used to authorize discharges of dredged or fill material into all waters of the United States and structures and work in all navigable waters of the United States to return the existing flood control to its maintenance baseline. Flood control facilities could be located in any type of waters of the United States, such riverine, lacustrine, palustrine, estuarine, and marine waters. The decision document for this NWP discusses, in general terms, the potential impacts of the authorized activities on all waters of the United States, including navigable waters of the United States. The national decision document also considers the potential benefits of maintaining these existing flood control management facilities so that they continue to perform their intended functions.

The estimated impact acreages in the national decision document for this NWP include both permanent and temporary impacts to waters of the United States, including navigable waters of the United States. Because this NWP authorizes only maintenance activities within the maintenance baselines established by district engineers, and the aquatic resources within the existing flood control facility generally recover after each maintenance activity is completed in accordance with the maintenance baseline that was previously approved by the district engineer, the activities authorized by this NWP generally result in temporary losses of waters of the United States. Permanent losses of waters of the United States caused by the original construction of these flood control facilities would have been addressed in the DA permit or other the authorization for the federal water resources development project, if such authorization was required for that construction. Therefore, most impacts to

waters of the United States authorized by this NWP will be temporary impacts to return these existing flood control facilities to their maintenance baselines.

The impacts of activities authorized by this NWP are more appropriately and accurately quantified in acres rather than linear feet, because these maintenance activities occur over areas of waters of the United States. Accurate quantification of impacts to waters of the United States is important aspect of tracking the individual and cumulative impacts of activities authorized by this NWP, to make more defensible determinations as to whether the individual and cumulative adverse environmental effects are no more than minimal.

This NWP is reissued as proposed.

NWP 32. Completed Enforcement Actions. The Corps did not propose any changes to this NWP. No comments were received on the proposed reissuance of this NWP. This NWP is reissued as proposed.

NWP 33. Temporary Construction, Access, and Dewatering. The Corps did not propose any changes to this NWP.

One commenter stated that this NWP should be reissued with no changes. One commenter said that this NWP should have a 1/10-acre limit for losses of waters of the United States and a 300 linear foot limit for losses of stream bed. One commenter said that this NWP contains vague language that gives the permittee discretion to determine how stringently various provisions will be followed, which may result in activities that cause more than minimal environmental effects. One commenter said that this NWP should be modified to include matting as a temporary fill for access, consistent with NWP 12 and the proposed new NWP C. One commenter stated that for activities in areas where state and/or federal threatened or endangered freshwater mussels are known to occur, this NWP should require pre-construction notification, as well as coordination with federal and state natural resource agencies.

This NWP authorizes only temporary construction, access, and dewatering activities, and does not authorize discharges of dredged or fill material into waters of the United States or structures or work in navigable waters of the United States that may result in permanent losses of waters of the United States. Permanent structures in navigable waters of the United States require separate DA authorization, either through individual permits, other NWPs, or regional general permits. The text of the NWP requires, after completion of construction, the removal of temporary fill material to an area that has no waters of the United States. If the authorized activity involves dredged material, the NWP requires the dredged material to be returned to its original location, and the affected area restored to pre-constructed elevations. Because of these specific requirements, the Corps believes that adding quantitative limits to this NWP is unnecessary. These specific requirements also help ensure that authorized activities result in no more than minimal individual and cumulative adverse environmental effects. Because this authorizes temporary fills for construction access for utility lines, as well as the use of mats for temporary access for utility lines when such mats require DA authorization, it is unnecessary to impose quantitative limits on this NWP.

Paragraph (c) of general condition 18 requires non-federal permittees to submit a pre-construction notification to the district engineer if any listed species (or species proposed for listing) or designated critical habitat (or critical habitat proposed such designation) might be affected or is in the vicinity of the activity, or if the activity is located in designated critical habitat or critical habitat proposed for such designation. Furthermore, paragraph (c) states that the permittee cannot begin work on the activity until notified by the district engineer that the requirements of the ESA have been satisfied and that the activity is authorized. Paragraph (c) of general condition 18 applies to mussel species that are listed, or proposed for listing, as endangered or threatened under the federal ESA. Potential effects to state-listed mussel species should be addressed through the permittee's compliance with state laws and regulations for state-listed species.

This NWP is reissued as proposed.

NWP 34. Cranberry Production Activities. The Corps did not propose any changes to this NWP. One commenter objected to the proposed reissuance of this NWP, stating it authorizes activities that will result in more than minimal adverse environmental effects and it does not require wetland functions to be maintained.

Cranberry production activities require maintenance of wetland conditions because cranberry plants are wetland-dependent species. This NWP authorizes discharges of dredged or fill material into waters of the United States that may temporarily disturb wetlands used for cranberry production, but this NWP does not authorize activities that may result in losses of wetlands. The wetlands used for cranberry production will continue to perform wetland functions, especially hydrologic and biogeochemical cycling functions. The habitat functions of the affected wetlands may be altered by the management of these wetlands to produce cranberries, with some species utilizing the habitat functions performed by cranberry wetlands, and other species not being able to use the habitat functions in cranberry wetlands. The species that cannot inhabit the cranberry production wetlands may use other wetlands in the vicinity of the cranberry farm for habitat.

This NWP is reissued as proposed.

NWP 35. Maintenance Dredging of Existing Basins. The Corps did not propose any changes to this NWP. One commenter said that permittees should be required to ensure that toxic substances are not released back into the water column through re-exposure during dredging activities. A few commenters stated that maintenance dredging at existing basins does not result in a discharge into waters of the United States, and should not require water quality certification from states. One commenter said that requiring dredged material to be discharged into areas that do not contain waters of the United States precludes using the dredged material from enhancing aquatic habitat, such as coastal marshes and freshwater marshes, through natural processes or through beneficial use projects. This commenter said that this NWP should be modified to allow dredged materials to be discharged into waters of the United States for beneficial uses, after federal and state natural resource agency coordination.

During dredging activities, chemical substances that were buried by sediments or attached to dredged sediments may be resuspended in the water column or may become solutes within the water column. Those chemical substances may have adverse effects to water quality. Those adverse effects are likely to be temporary because the suspended sediments are likely to settle back onto the benthos and chemicals present as solutes in the water column are likely to be dispersed by currents, tides, and other causes of water movement. Under Section 401 of the Clean Water Act, certifying authorities may determine that a dredging activity may result in a discharge into waters of the United States and require the project proponent to obtain an individual water quality certification or waiver unless the certifying authority has issued water quality certification for the issuance of a general permit that authorizes the dredging activity. Water quality certifications for activities authorized by this NWP will help ensure that any

discharges that may be caused by those dredging activities comply with applicable water quality requirements.

Since it was first issued in 1991 (56 FR 59144), this NWP has been issued only under the authority of Section 10 of the Rivers and Harbors Act of 1899. This NWP has never been issued or reissued under the authority of Section 404 of the Clean Water Act. Therefore, this NWP does not authorize discharges of dredged or fill material into waters of the United States, including activities involving redepositing the dredged material into waters of the United States for beneficial uses or other purposes. Beneficial use of material dredged under the section 10 authorization provided by NWP 35 may be authorized by other NWPs issued under the authority of section 404, such as NWP 27, or other forms of DA authorization under section 404, including individual permits and regional general permits. If an individual permit is required for the beneficial use of dredged material, then there will be coordination with federal and state agencies under the individual permit review process.

This NWP is reissued as proposed.

NWP 36. Boat Ramps. The Corps did not propose any changes to this NWP. One commenter recommended reinstating the restriction for one boat ramp for contiguous properties under the same ownership to reduce the potential for fragmentation of nearshore habitats. One commenter said that for previously permitted structures, the Corps should also specify that repair and replacement activities are limited to the minimum necessary to accomplish the function of the original boat ramp. This commenter also stated that for new boat ramps, or for expansions of existing boat ramps, the Corps should impose conditions to ensure that new or modified boat ramps result in no more than minimal individual and cumulative adverse environmental effects.

This NWP was first issued in 1991 (see 56 FR 59144), and it never had a provision limiting the number of boat ramps to one boat ramp per set of contiguous properties under the same ownership. Therefore, the change suggested by the commenter would be a new provision for this NWP. The Corps does not believe that such a provision is necessary to ensure that the construction of boat ramps authorized by this NWP will result in no more than minimal individual and cumulative adverse environmental effects. During the review of PCNs for proposed NWP 36 activities, district engineers will evaluate potential adverse environmental effects, including the possible fragmentation of shoreline habitats and potential disruptions on the movements of aquatic organisms along the shore.

This NWP has two quantitative limits for authorized activities: A 50 cubic yard limit for discharges of dredged or fill material into waters of the United States, and a 20-foot limit for the width of the boat ramp. Both of these quantitative limits can be waived by district engineers after they review PCNs for proposed boat ramps under this NWP. Waivers of these quantitative limits may only occur when district engineers make written determinations, after conducting agency coordination under paragraph (d) of general condition 32, that the proposed activities will result in no more than minimal individual and cumulative adverse environmental effects. The Corps has modified the first paragraph of this NWP to clarify that in addition to the construction of new boat ramps, it also authorizes the repair or replacement of existing boat ramps. As with the construction of new boat ramps, to be authorized by NWP the repair or replacement of boat ramps must comply with the requirements of this NWP, including the quantitative limits, and result in no more than minimal individual and cumulative adverse environmental effects.

This NWP is reissued with the modification discussed above.

NWP 37. Emergency Watershed Protection and Rehabilitation. The Corps did not propose any changes to this NWP. No comments were received on the proposed reissuance of this NWP. This NWP is reissued as proposed.

NWP 38. Cleanup of Hazardous and Toxic Waste. The Corps did not propose any changes to this NWP. No comments were received on the proposed reissuance of this NWP. This NWP is reissued as proposed.

NWP 41. Reshaping Existing Drainage and Irrigation Ditches. The Corps proposed to modify this NWP by adding irrigation ditches. Several commenters expressed support for the proposed changes to this NWP. Several commenters stated that the Corps should make additional changes to this NWP to ensure that it is consistent with the current regulatory definition of ''waters of the United States'' for the purposes of the Clean Water Act at 33 CFR part 328. Several commenters said that the Corps should clarify in the final rule that the addition of irrigation ditches to this NWP does not affect the Clean Water Act Section 404(f) exemption for irrigation ditches. These commenters requested that the Corps explain how reshaping ditches for the purpose of improving water quality aligns with the current interpretation of the Clean Water Act Section 404(f) exemption for ditch maintenance, which allows for minor changes to cross sections of ditches to conform to current engineering standards, as long as the ditch modifications do not result in the drainage, degradation, or destruction of additional jurisdictional waters.

The purpose of this NWP is to authorize discharges of dredged or fill material into waters of the United States to reshape existing drainage and irrigation ditches to improve water quality by regrading the drainage or irrigation ditch with gentler side slopes that can reduce erosion, increase growth of vegetation within the ditch, and increase uptake of nutrients and other substances by vegetation. This NWP applies to drainage ditches and irrigation ditches that are waters of the United States. If a drainage ditch or irrigation ditch is not subject to Clean Water Act jurisdiction under the current regulations defining ''waters of the United States'' at 33 CFR part 328, then DA authorization (including the DA authorization provided by this NWP) is not required for discharges of dredged or fill material that reshape the drainage or irrigation ditch to improve water quality.

This NWP does not authorize ditch maintenance activities specifically, because it authorizes discharges of dredged or fill material into waters of the United States to change the shape of existing drainage or irrigation ditches to facilitate the removal of nutrients, other chemicals, and sediments from the water column to improve water quality. This NWP authorizes discharges of dredged or fill material into waters of the United States to change the shape of jurisdictional ditches to improve water quality, which is a different purpose than the purpose identified in the current memorandum interpreting the Clean Water Act Section 404(f) exemption for ditch maintenance (*i.e.,* conforming with current engineering standards to improve ditch stability). Therefore, the activities authorized by this NWP are distinct from the activities identified in the current guidance interpreting the Clean Water Act Section 404(f)(1)(C) exemption for ditch maintenance.

One commenter said that there may be no projects that might utilize the proposed changes to this NWP and requested that the Corps provide specific examples of projects involving the reshaping of irrigation ditches to improve water quality. One commenter stated that the Corps should add a provision to this NWP that prohibits the

reshaping of irrigation ditches that increases diversions of water that are not allowed under existing water rights or do not conform with state water law.

As discussed in the Regulatory Impact Analysis for this final rule, the Corps anticipates that there may be a small number of irrigation ditches (estimated to be five per year) that may be reshaped to improve water quality through the authorization provided by this NWP. The Corps declines to add restrictions to this NWP regarding quantities of diverted water, potential impacts to existing water rights, or situations where irrigation ditch reshaping activities might not conform with state water law. State government authorities are the appropriate entities for enforcing water rights and other provisions of state water laws.

One commenter objected to the proposed reissuance of this NWP, as well as the proposed modification, stating that the activities authorized by this NWP may adversely affect salmon and trout that inhabit ditches. This commenter said that PCNs should be required for all activities authorized by this NWP so that the Corps can evaluate potential effects on salmon and trout, and if necessary add conditions to the NWP authorization to protect those species. This commenter also stated that the Corps should add quantitative limits to this NWP to limit the length of ditch reshaped and the frequency of ditch reshaping activities.

Activities authorized by this NWP are subject to the requirements of general condition 18, which addresses compliance with the federal ESA. Paragraph (c) of general condition 18 requires a non-federal permittee to submit a pre-construction notification to the district engineer if any listed species (or species proposed for listing) or designated critical habitat (or critical habitat proposed such designation) might be affected or is in the vicinity of the activity, or if the activity is located in designated critical habitat or critical habitat proposed for such designation. This includes salmon and trout species listed as endangered or threatened under the ESA, as well as salmon and trout species that may be proposed for listing under the ESA. The Corps does not believe it is necessary to impose quantitative limits on this NWP, because this NWP is limited to reshaping existing drainage and irrigation ditches to improve water quality, and these activities do not result in permanent losses of waters of the United States.

One commenter stated that the Corps should modify the NWP to cite the statutory exemptions that could apply under Clean Water Act Section 404(f). Several commenters recommended adding a Note to this NWP similar to the Notes in NWPs 3, 12, 14, 30, and 40, stating that certain discharges may qualify for an exemption under Section 404(f) of the Clean Water Act and therefore do not require DA authorization under section 404.

The purpose of this NWP is to authorize discharges of dredged or fill material into waters of the United States for reshaping existing drainage and irrigation ditches when those activities are not eligible for any of the exemptions in Section 404(f) of the Clean Water Act. The Corps declines to add the suggested Note to this NWP because it would be contrary to the reason the NWP was first issued in 2000 (see 65 FR 12891). This NWP was issued to provide an incentive for landowners to reshape their ditches to improve water quality, rather than maintaining those ditches in a manner that qualifies for the Clean Water Act Section 404(f)(1)(C) exemption. Adding the suggested Note may discourage landowners from reshaping existing ditches to improve water quality by highlighting the availability of the ditch maintenance exemption.

This NWP is reissued as proposed.

NWP 45. Repair of Uplands Damaged by Discrete Events. The Corps did not propose any changes to this NWP. One commenter said that the restoration of upland areas should be accomplished with fill material taken from uplands, and limit minor dredging to no more than 25 cubic yards to be consistent with the limit in NWP 19. One commenter stated that for shoreline erosion, the establishment of living shorelines should be encouraged over the reclamation of eroded lands through the use of fill material and hard structures.

The Corps does not agree that the restoration of uplands damaged by storms and other discrete events should be required to utilize only fill material taken from upland sites. Sediment that moved from adjacent uplands into the waterbody because of erosion or mass wasting caused by storms or other discrete events should be available for repairing the damaged uplands. Using that sediment to repair the affected uplands can help restore the waterbody by removing sediment that may be blocking the waterbody or covering aquatic habitat within that waterbody. It can also help reduce downstream sediment loads, by putting that sediment back onto the damaged upland areas where it can be stabilized before it is transported downstream and potentially impair downstream water quality.

The NWP limits dredging to the amount necessary to restore the damaged upland area, restricting the amount of material dredged so that it is proportional to the amount of upland damaged by the discrete event. That dredging limit provides flexibility to address the amount of damaged uplands, and prevents situations where the amount of authorized dredging needed to effectively repair the damaged uplands and the waterbody would require individual permits. In other words, limiting dredging to 25 cubic yards may discourage effective means of repairing the damaged uplands and restoring adjacent portions of the waterbody.

This NWP limits bank stabilization activities to the contours or ordinary high water mark that existed before the damage to the uplands occurred. In many circumstances, this limit precludes the use of living shorelines as a bank stabilization measure in coastal areas. If a landowner wants to install a living shoreline next to uplands repaired through activities authorized by NWP 45, then he or she may submit a PCN under NWP 54, which authorizes living shorelines. Bank stabilization within the limits of NWP 45 can be accomplished through other approaches, such as bioengineering or other forms of vegetative stabilization.

This NWP is reissued as proposed.

NWP 46. Discharges in Ditches. The Corps did not propose any changes to this NWP. Several commenters stated that the text of this NWP should clarify when this NWP can be used for discharges of dredged or fill material into upland ditches because it seems to be inconsistent with the current definition of ''waters of the United States'' in the Corps' regulations at 33 CFR part 328. A few commenters said that the provisions of this NWP should be consistent with the current regulations defining ''waters of the United States'' and the current guidance on ditches and the exemptions under Section 404(f) of the Clean Water Act. Several commenters stated that the Corps should modify this NWP to acknowledge that certain discharges related to activities in ditches may qualify for exemptions from permitting under Section 404(f) of the Clean Water Act. These commenters suggested adding a Note to this NWP similar to the notes regarding the Clean Water Act Section 404(f) exemptions in NWPs 3, 12, 14, 30 and 40.

This NWP authorizes discharges of dredged or fill material into non-tidal ditches that meet the four criteria in the

first paragraph of the NWP, including the fourth criterion (*i.e.,* the ditch must be a water of the United States). If the ditch constructed in uplands is not a water of the United States, in accordance with the Corps' current regulations at 33 CFR part 328 that define ''waters of the United States,'' then DA authorization (including the DA authorization provided by NWP 46) is not necessary to discharge dredged or fill material into that ditch. This NWP authorizes activities that are not eligible for any of the exemptions under Section 404(f) of the Clean Water Act. Therefore, it is not necessary to add a Note to this NWP that address the section 404(f) exemptions. This NWP was issued in 2007 (see 72 FR 11190) to provide DA authorization to fill a category of ditches constructed in uplands that meet the four criteria listed in the first paragraph of the NWP. Filling these ditches to convert them back to uplands would likely trigger the recapture provision of Section 404(f)(2) of the Clean Water Act and therefore not be exempt from section 404 permitting requirements. If the project proponent wants to discharge dredged or fill material to maintain the ditch, and not convert it into uplands, the proposed discharge might be eligible for an exemption under section 404(f) depending on case-specific circumstances. Therefore, the Corps does not believe that there would be any benefit to adding a Note to this NWP that discusses the section 404(f) exemptions.

One commenter said that the acreage limit of this NWP should be reduced to 1/2-acre to ensure that the activities authorized by this NWP result in no more than minimal individual and cumulative adverse environmental effects. One commenter stated that compensatory mitigation should be required for losses of waters of the United States greater than 1/10-acre.

The Corps is retaining the 1-acre limit that was established for this NWP when it was first issued in 2007. During the years this NWP has been in effect, the one acre limit has been effective in ensuring that discharges of dredged or fill material into the non-tidal ditches that satisfy four criteria in the first paragraph of this NWP result in losses of waters of the United States that have no more than minimal individual and cumulative adverse environmental impacts. Division engineers can add regional conditions to this NWP to impose an acreage limit that is less than one acre, to ensure that activities authorized in the region will have no more than minimal individual and cumulative adverse environmental effects. During the review of PCNs for proposed NWP 46 activities, district engineers can require compensatory mitigation to offset the permitted losses of waters of the United States, in accordance with 33 CFR 330.1(e)(3) and general condition 23.

This NWP is reissued as proposed.

NWP 49. Coal Remining Activities. The Corps proposed to modify this NWP by removing the provision that requires the permittee to obtain written verification from the district engineer before proceeding with the authorized activity to make this NWP consistent with the other NWPs that have a default authorizations when a district engineer does not respond to a complete PCN within 45 days of receiving that PCN from the project proponent. The Corps also proposed to remove the text referring to integrated permit processing procedures.

One commenter stated support for reissuing this NWP. Many commenters expressed opposition to the proposal to remove the provision that requires the permittee to obtain written verification from the district engineer before commencing the authorized activity. Several commenters said they support removing the requirement for the permittee to obtain written verification from the district engineer before proceeding with the authorized activity, so that a default authorization occurs if the district engineer does not respond to a complete PCN within 45 days.

The Corps has retained the provision that requires the permittee to obtain written authorization from the district engineer prior to commencing the authorized activity because coal remining activities can vary substantially in size and can cover large areas. Additional time may be needed for the project proponent to demonstrate to the district engineer that the authorized activity will result in a net increase in aquatic resource functions. This NWP has no acreage limit for losses of waters of the United States. In contrast, NWP 21 (surface coal mining activities) and NWP 50 (underground coal mining activities) have a 1/2-acre limit for losses of waters of the United States. The requirement for permittees to obtain written authorization before proceeding with the NWP 21 or 50 activity was removed in the final rule published in the January 13, 2021, issue of the **Federal Register** (86 FR 2744) because these NWPs have the additional safeguard of the 1/2-acre limit if a default authorization occurs through a district engineer not responding to a complete PCN within 45 days.

One commenter opposed to the removal of stream mitigation requirements from this NWP. One commenter said that PCNs should not be required for the activities authorized by this NWP. One commenter supported removing the text referring to integrated permit processing procedures.

The Corps did not propose to remove any stream mitigation requirements from this NWP. The activities authorized by this NWP must result in net increases in aquatic resource functions. Stream or wetland rehabilitation or enhancement may be a component of the coal remining activity that helps achieve the required net increase in aquatic resource functions. Mitigation requirements for NWP activities is determined by district engineers on a case-by-case basis through the provisions of 33 CFR 330.1(e)(3) and general condition 23. The Corps believes that PCNs are necessary for all activities authorized by this NWP to provide district engineers the opportunity to review proposed activities and ensure that the activities that comprise the overall mining plan result in net increases in aquatic resource functions. The Corps has removed the text that refers to integrated permit processing procedures because those procedures were not developed for past versions of NWP 49.

One commenter recommended modifying the text of this NWP to state that new mining must not exceed 40 percent of the remined area and the additional area necessary to carry out the reclamation of a previously mined area. One commenter noted that no work can begin under this NWP unless the coal remining activity is approved by the Department of the Interior Office of Surface Mining Reclamation or Enforcement, or by states with approved programs under Title IV or V of the Surface Mining Control and Reclamation Act of 1977, and that final approval by these agencies is not necessary before submitting a PCN to the district engineer.

The Corps is retaining the text in the NWP that states that the total area disturbed by new mining must not exceed 40 percent of the total acreage covered by both the remined area and the additional area necessary to carry out the reclamation of the previously mined area. The Corps acknowledges that permittees should not begin the authorized work if the activities authorized by this NWP also require authorization by other federal, state, or local government agencies (see paragraph 2 of Section E, Further Information) and those other required authorizations have not been issued. The project proponent can submit a PCN for a proposed NWP 49 activity to the district engineer prior to obtaining

required authorizations from either the Office of Surface Mining Reclamation or Enforcement, or a state with an approved program under Title IV or V of the Surface Mining Control and Reclamation Act of 1977.

This NWP is reissued with the modification discussed above.

NWP 53. Removal of Low-Head Dams. The Corps did not propose any changes to this NWP. Several commenters expressed support for the reissuance of this NWP. One commenter said that the Corps should revise this NWP so that it clearly states that it may be used to authorize compensatory mitigation projects that generate stream mitigation credits, because dam removal and stream restoration projects help spur economic activity in rural regions, improve water quality, and deliver resiliency benefits to communities. One commenter said that the removal of low-head dams could affect water rights determined by the state. One commenter stated that this NWP should be modified to include requirements for management of accumulated sediment prior to and during removal of low-head dams to ensure that downstream water quality is minimally adversely impacted by the removal of low-head dams.

The Corps does not believe it is necessary to modify this NWP to state that it can be used to authorize discharges of dredged or fill material into waters of the United States and/or structures and work in navigable waters of the United States for low-head dam removals conducted to rehabilitate rivers and streams to provide compensatory mitigation for DA permits. Low-head dam removals can be conducted for permittee-responsible mitigation, mitigation banks, or in-lieu fee projects to generate compensatory mitigation credits that offset losses of aquatic resource functions and services caused by activities authorized by DA permits. The Corps recognizes that stream restoration projects, including removals of low-head dams, provide a variety of ecological and economic benefits to communities. However, it is not necessary to explicitly identify those benefits in the text of the NWPs. Concerns about potential impacts of low-head dam removals on state issued water rights are more appropriately addressed through the state laws and regulations that govern those water rights, and the effects that specific activities may have on water rights. Permittees are responsible for complying with applicable federal, tribal, state, and local government laws, regulations, and other requirements.

The text of this NWP does not include requirements for the management of sediments that may be released after the removal of a low-head dam. Requirements for the management of sediments that may be released downstream after the low-head dam is removed is more appropriately determined on a case-by-case basis when the district engineer reviews the PCN for the proposed NWP 53 activity. In general, low-head dams have low storage capacities and large amounts of sediment are unlikely to be released to downstream waters when the low-head dam is partially or completely removed. In addition, sediment releases caused by the removal of low-head dams generally have temporary impacts because the sediment is transported downstream by flowing water and over time those sediments will be distributed throughout downstream tributaries as the stream network recovers from the removal of the low-head dam.

Water quality concerns, including water quality concerns regarding sediment releases that may occur during the removal of the low-head dam and after the low-head dam is removed, are more appropriately addressed through the water quality certification process under Section 401 of the Clean Water Act. For those activities where the certifying authority denied water quality certification for the reissuance of NWP 53, the project proponent must obtain a water quality certification or waiver for any discharges into waters of the United States that may occur as a result of the removal of the low-head dam (see general condition 25). The water quality certification may include conditions, such as sediment management requirements, to ensure that those discharges comply with applicable water quality requirements.

A few commenters stated that the Corps should clarify the definition of low-head dam to be more expansive in the types of structures that can be removed under this NWP. One of these commenters suggested broadening the definition of ''low-head dam'' to include different low-head dam configurations or to add a specific height to the definition of ''low-head dam.'' Two of these commenters suggested modifying the definition of ''low-head dam'' as follows:

For the purposes of this NWP, the term ''low-head dam'' is generally defined as a dam or weir built across a stream to pass flows from upstream over all, or nearly all, of the width of the dam crest and does not have a separate spillway or spillway gates, but it may have an uncontrolled spillway. The dam crest is the top of the dam from left abutment to right abutment and will most often be less than 15 feet in height for small streams and 25 feet in height for medium-sized tributaries. A low-head dam may have been built for a range of purposes (*e.g.,* check dam, mill dam, irrigation, water supply, recreation, hydroelectric, or cooling pond), but in all cases, it provides little to no storage function.

In response to these comments, the Corps has modified the definition of ''low-head dam'' that is in the text of this NWP. The Corps has adopted much of the definition suggested above, except for the recommended maximum height requirements for dams in small streams and medium-sized tributaries. The Corps declines to include maximum height requirements because the heights suggested by commenters might apply to dams that are not low-head dams. In addition, the terms ''small stream'' and ''medium-sized tributary'' are difficult to define. ''Small'' versus ''medium'' are relative terms and are likely to pose additional challenges in implementing a clear, consistent definition of ''low-head dam.'' The definition of ''low-head dam'' with the modifications made in response to public comments focuses on structural features characteristic of most low-head dams, instead of dimensions that represent types of dams other than low-head dams. District engineers have discretion in determining whether proposed dam removal involves a low-head dam and thus qualifies for NWP 53 authorization. Even with the exclusion of the suggested maximum height requirements, the revised definition of ''low-head dam'' may broaden the utility of this NWP to facilitate the removal of low-head dams that may not have been covered by the 2017 version of this NWP.

One commenter stated that other federal and state natural resource agencies should be provided opportunities for review and comment on all PCNs for this NWP that are submitted to district engineers. One commenter requested clarification on whether any specific removals of low-head dams have resulted in increases in ecological functions. One commenter asked that the Corps explain the basis for establishing the 1/2-acre limit for this NWP. This commenter asked whether there is a limit to either the area of the impoundment that is dewatered as a result of the removal of a low-head dam, or the area where significant hydrological changes would occur as a result of the removal of a low-head dam. This commenter also requested clarification on how the Corps calculates the impact acreage for activities authorized by this NWP, including impacts that may occur upstream and downstream of the low-

head dam and its impoundment after the low-head dam is removed.

The Corps declines to modify this NWP to require district engineers to coordinate PCNs for this NWP with federal and state natural resource agencies. Corps district staff have the capability to review these proposed activities and determine whether they qualify for NWP authorization. District engineers have the discretion to coordinate with federal and state resource agencies on a case-by-case basis, if they believe such coordination would be beneficial in reaching a decision on a particular PCN. Coordination with federal and state agencies may also occur in other circumstances, such as the water quality certification process for discharges into waters of the United States authorized by this NWP. District engineers will review PCNs for proposed activities, and if a district engineer determines that the proposed removal of a low-head dam may affect endangered or threatened species or designated critical habitat, he or she will conduct ESA Section 7 consultation with the U.S. Fish and Wildlife Service and/or the National Marine Fisheries Service, as appropriate.

The potential increases in ecological functions that may result from the removal of low-head dams are discussed in the national decision document for the reissuance of this NWP. The national decision document cites a number of reviews and studies that have evaluated the ecological benefits that can result from the removal of low-head dams. This NWP has no acreage limit because the removal of low-head dams helps restore the structure, functions, and dynamics of rivers and streams. The removal of low-head dams also benefits public safety by reducing potential drowning risks for swimmers and users of small watercraft, such as kayaks. The 1/2-acre limit that is in other NWPs, such as NWP 29 for residential developments and NWP 39 for commercial and institutional developments, does not apply to this NWP. The impact acreages for activities authorized by this NWP are generally calculated by determining the acreage of the footprint of the low-head dam, the acreage of the former impoundment that will be restored to a free-flowing river or stream channel, and any additional acreage of the impoundment that will dewatered after the low-head dam is removed. The dewatered areas of the former impoundment may develop riparian areas and floodplains, including adjacent riverine wetlands. There may be other indirect effects upstream and downstream of the low-head dam and its impoundment, but the acreage of waters subject to those indirect effects would not normally be calculated because of the difficulties in quantifying those indirect effects.

This NWP is reissued with the modification discussed above.

NWP 54. Living Shorelines. The Corps did not propose any changes to this NWP. One commenter stated support for the reissuance of this NWP because living shorelines provide environmental, societal, and economic benefits that are not provided by hard bank stabilization structures. One commenter stated that paragraph (d) of this NWP should be modified to add elevation as a factor for determining which native plants are appropriate for current site conditions if the permittee is planting the living shoreline. One commenter said that the requirement for living shorelines to include a substantial biological component provides no meaningful guidance and would result in the authorization of any project that includes a minor amount of vegetation planting.

The Corps is reissuing this NWP with minor changes made in response to comments received on the 2020 Proposal. The Corps has added ''elevation'' to paragraph (d) of this NWP because elevation is another factor to consider when deciding which native species to plant in a living shoreline if the biological component of the living shoreline consists of plants. The NWP takes a qualitative approach to characterizing living shorelines (*i.e.,* having a substantial biological component) rather than specifying a minimum quantitative requirement because there can be considerable variability in the designs for living shorelines. The types of biological components used for living shorelines can also vary, from various types of plants (*e.g.,* marsh grasses, mangroves) and different types of animals (*e.g.,* oysters). There is no one-size-fits-all approach to living shorelines that would support a stringent quantitative approach for the determining the minimum amount of biological components in a bank stabilization activity to be considered for a living shoreline.

A few commenters objected to the proposed reissuance of this NWP, stating that it has the potential to cause extensive destruction and alteration of irreplaceable nearshore habitats. These commenters said that these activities should require individual permits. One commenter said that this NWP violates Section 404(e) of the Clean Water Act because it authorizes activities that are not similar in nature.

This NWP provides DA authorization for an approach to managing shoreline erosion that can provide more aquatic resource functions and services than other approaches to managing shoreline erosion control, such as bulkheads and revetments. While the construction of living shorelines can involve placing considerable amounts of dredged or fill material into jurisdictional waters and wetlands, completed living shorelines can provide habitat functions, as well as other ecological functions such as biogeochemical cycling functions. There may be trade-offs when the construction of living shorelines changes subtidal habitats (*e.g.,* unvegetated shallow waters) into intertidal habitats (*e.g.,* intertidal marshes). Riparian landowners have an inherent right to protect their properties from erosion (see 33 CFR 320.4(g)(2), and living shorelines provide an alternative means of managing shore erosion that can provide greater environmental benefits such as intertidal wetland habitat and shellfish reef habitat compared to bulkheads and revetments.

This NWP authorizes a specific category of activities: discharges of dredged or fill material into waters of the United States and structures or work in navigable waters of the United States for the construction and maintenance of living shorelines. Those activities are similar in nature because they serve a common purpose (*i.e.,* managing shoreline erosion) and involve a common set of activities (*e.g.,* fills to construct wetlands, fills to protect constructed and existing wetlands, and fills and structures to construct reefs) that dissipate wave energy and reduce erosion. In addition, these fills and structures are generally limited to nearshore areas, where they help manage shoreline erosion.

One commenter said that this NWP should be modified to include the authorization of temporary structures, fill, and work, similar to the text provided in NWP 13. One commenter stated that the text of the NWP allows concrete and other artificial structures, which are not native materials. One commenter said that the NWP should require the permittee to ensure that the activity maintain the natural continuity of the land-water interface, retain, or enhance shoreline ecological processes, and not result in undue harm to recognized aquatic resources located within or adjacent to the proposed project sites.

Nationwide permit 33 can be used to authorize temporary structures, fill, and work to assist in the construction of living shorelines authorized by NWP 54. All NWP 54 activities involving the

construction of new living shorelines require PCNs, whereas the construction of bank stabilization measures under NWP 13 require PCNs only in certain circumstances, such as discharges of dredged or fill material into special aquatic sites or bank stabilization activities greater than 500 linear feet in length. The text authorizing temporary structures, fills, and work was added to NWP 13 because not all NWP 13 activities require PCNs, and that text provides efficiency because permittees no longer need to use NWP 33 (which may require PCNs) with the NWP 13 authorization to construct the bank stabilization activity. Retaining the ability to use NWP 33 to authorize temporary structures, fills, and work for new living shorelines authorized by NWP 54 does not impose additional burdens on the regulated public.

The text of this NWP requires that the living shoreline consist mostly of native material. It does not completely prohibit the use of artificial materials. While the text of the NWP does not explicitly identify concrete as an acceptable material for use in living shorelines, it does not prohibit the use of concrete because concrete may be a component of artificial reef structures that are used for some types of living shorelines. Living shorelines may include artificial structures (*e.g.,* sills, reefs, coir logs or mats) that do not completely resemble structural features found in nature, but those artificial structures can consist of native materials (*e.g.,* stone, oyster shells, natural fibers) to a large degree.

Living shorelines are an example of nature-based solutions, which are actions to address societal problems such as erosion in coastal communities using natural or modified ecosystems. Living shorelines are modified ecosystems that are comprised of a combination of living and engineered components. Living shorelines provide varying degrees of ecological functions and services and help maintain to some extent the natural continuity of the interface between coastal lands and coastal waters. With the exception of maintenance activities, all activities authorized by this NWP requires PCNs to district engineers. District engineers will review those PCNs to determine whether the proposed activities will result in no more than minimal individual and cumulative adverse environmental effects, including adverse effects to coastal aquatic resources.

One commenter stated that the 30 foot limit for structures and filled areas extending into the waterway from the mean low water line in tidal waters or the ordinary high water mark in non-tidal waters is arbitrary, and that the Corps should establish the limit for structures and fills extending into the waterway to a depth contour appropriate for attenuating wave energy consistent with the slope of the shoreline. One commenter said that the Corps should replace the 30-foot and 500 linear foot limits with a 1/2-acre limit.

The Corps is retaining the 30 foot limit for structures and fills extending into the waterway and the 500 linear foot limit for the length of shoreline along which a living shoreline can be constructed. The Corps is also retaining the ability for district engineers to waive these 30-foot and 500 linear foot limits when a district engineer reviews the PCN for a proposed NWP 54 activity and determines that the proposed activity will result in no more than minimal individual and cumulative adverse environmental effects. These quantitative limits and the ability of district engineers to waive these limits are intended to provide flexibility for the design and construction of living shorelines that are expected to be effective in reducing erosion at a specific site, taking into numerous variables. For living shorelines, those variables include, but are not limited to: Fetch, water depths near the shore, substrate characteristics, site topography, and the extent of coastal development in the project area (Saleh and Weinstein 2016). Activities authorized by this NWP must comply with paragraph (a) of general condition 23, which requires permittees to design and construct authorized activities to avoid and minimize adverse effects, both temporary and permanent, to waters of the United States to the maximum extent practicable at the project site (*i.e.,* on site).

The Corps believes the 30 foot and 500 linear foot limits are more appropriate for living shorelines than a 1/2-acre limit because living shorelines are constructed along the shore. In addition, paragraph (e) of the NWP requires discharges of dredged or fill material into waters of the United States and the construction of structures in navigable waters of the United States to be the minimum necessary for the establishment and maintenance of the living shoreline, to reduce the amount of encroachment into the waterway.

One commenter said that while the NWP might be beneficial for coastal resources found along the Gulf of Mexico or the Atlantic Coast, it is not appropriate for the Puget Sound or the Washington coast because it allows for construction of structures and fill that would adversely affect significant nearshore resources and habitats and does not have minimal direct, indirect, or cumulative impacts. This commenter expressed support for streamlining a process to install shoreline stabilization that protects nearshore habitat for salmon and shellfish.

Landowners that want to reduce erosion at their shorelines are not required to construct living shorelines. They can choose to use other techniques to manage erosion at their waterfront properties. Potential adverse effects to nearshore resources and habitats caused by discharges of dredged or fill material into waters of the United States or structures or work in navigable waters of the United States are similar along the various coasts of the United States in terms of functional impacts (*e.g.,* filling or altering nearshore habitats or installing reef structures that alter subtidal habitat), although the species that may be affected by these activities may differ by region. If a landowner on the west coast wants to construct a living shoreline to manage erosion at his or her property, a PCN must be submitted to the district engineer. The district engineer will review the PCN and determine whether the proposed activity will result in no more than minimal individual and cumulative adverse environmental effects.

Living shorelines have been used in the west coast of the United States, including Washington State. NOAA has established a living shorelines project map to provide information on more than 150 living shoreline projects around the country.[2] Three living shoreline projects in Washington State were shown on that map when it was viewed by the Corps on July 14, 2021. In other areas of the west coast, living shorelines consisting of eelgrass and Olympia oysters have been implemented in San Francisco Bay (Boyer et al. 2017). Green shores (Emmett et al. 2017) is another approach to shore erosion management has been implemented in Washington State, and green shore projects may qualify for authorization under NWP 54 if they include a substantial biological component, such as plantings in tidal waters subject to the Corps' jurisdiction. Green shores use materials such as coarse sand, gravel, cobbles, logs, and plantings, as well as slope modifications to dissipate wave energy, to control shoreline erosion while providing habitat and other ecological functions along the shoreline while reducing erosion and potential risks to buildings and infrastructure. Proposed green

[2] *https://www.habitatblueprint.noaa.gov/living-shorelines/project-map/* (accessed July 14, 2021).

shores activities that do not have the substantial biological component required for authorization under NWP 54 may be authorized by NWP 13, which authorizes a variety of techniques for bank stabilization.

Living shorelines can provide habitat that is utilized by salmon and shellfish. Bank stabilization activities can be designed to provide intertidal habitat (*e.g.,* pocket beaches) and subtidal habitat that is utilized by salmon and other fish species for foraging and nursery activities (*e.g.,* Toft et al. 2013). Living shorelines can include pocket beaches and may have unvegetated beaches protected by reef structures inhabited by oysters or other aquatic organisms. Living shorelines can be another means of managing shore erosion while providing intertidal habitat and shallow subtidal habitat for fish and other aquatic species for refuge, feeding, and nursery functions (Gittman et al. 2016). Reef structures used as part of a living shoreline, as well as other habitats such as wetlands that may be components of living shorelines, can provide habitat for colonization by bivalve molluscs (Bilkovic and Mitchell 2013).

One commenter said that PCNs should be required for the repair and maintenance of existing living shorelines. One commenter stated that waivers should not be issued by district engineers without coordination with federal and state natural resource agencies. One commenter expressed concern about waivers because they would remove any limits on how far living shorelines can extend into the waterway, how long those living shorelines are, and how much dredged or fill material is placed into special aquatic sites.

The Corps maintains its position that PCNs should not be required for maintenance of existing living shorelines because the adverse environmental effects caused by these maintenance activities are likely to be no more than minimal, individually and cumulatively. In addition, periodic maintenance is an important component of sustaining the effectiveness of living shorelines in managing erosion and sustaining the living components of a living shoreline. An exception occurs for maintenance activities that require DA authorization that trigger the PCN requirements in paragraph (c) of general condition 18, which addresses compliance with the ESA. Paragraph (c) of general condition 18 requires non-federal permittees to submit a pre-construction notification to the district engineer if any listed species (or species proposed for listing) or designated critical habitat (or critical habitat proposed such designation) might be affected or is in the vicinity of the activity, or if the activity is located in designated critical habitat or critical habitat proposed for such designation.

For proposed NWP 54 activities in which the project proponent is requesting a waiver of the 30 foot or 500 linear foot limits, district engineers will coordinate the PCNs with federal and state agencies in accordance with the procedures in paragraph (d) of general condition 32. The federal and state agencies will provide their views on whether the proposed activity will result in no more than minimal individual and cumulative adverse environmental effects. For NWP 54 activities where agency coordination is not required, district engineers will apply the 10 criteria in paragraph 2 of section D, District Engineer's Decision, to determine whether the proposed activities will result in no more than minimal individual and cumulative adverse environmental effects.

This NWP is reissued with the modification discussed above.

NWP E. Water Reclamation and Reuse Facilities. The Corps proposed to issue this new NWP to authorize discharges of dredged or fill material into waters of the United States for the construction, expansion, and maintenance of water reclamation and reuse facilities.

Several commenters stated that although discharges of dredged or fill material into waters of the United States for the construction, expansion, and maintenance of water reclamation and reuse facilities may be authorized by other existing NWPs, they support the issuance of proposed new NWP E because it provides additional clarity and streamlines the authorization process for these facilities. A few commenters said that there is no need to issue proposed new NWP E because water reclamation and reuse facilities may be constructed, expanded, or maintained through existing NWPs. One commenter stated that water reuse facilities are typically attendant features of larger developments and should be permitted as part of the overall development. Several commenters expressed their support for the issuance of proposed NWP E as long as it applies to groundwater recharge and replenishment projects without restrictions on the origin or mix of sources of water being recharged, including water from outside of the watershed.

The Corps is issuing this new NWP to authorize discharges of dredged or fill material into waters of the United States for water reclamation and reuse facilities, to help streamline the authorization process for the construction, expansion, and maintenance of these facilities. The water reclamation and reuse facilities constructed, expanded, or maintained through the discharges of dredged or fill material into waters of the United States authorized this NWP may be for non-potable water reuse and potable water reuse. Water reclamation and reuse facilities can be an important tool for adapting to the effects of climate change, such as changes in precipitation patterns that may affect water availability in areas of the country. Water reclamation and reuse facilities help conserve water, which may be beneficial as water availability changes or increases in water demand occur. The Corps recognizes that water reclamation and reuse facilities can be authorized as attendant features of other activities authorized by NWP, such as residential developments (NWP 29), commercial and institutional developments (NWP 39), agricultural activities (NWP 40), and recreational facilities (NWP 42). Despite the potential for water reclamation and reuse facilities to be authorized along with buildings and other features authorized by other NWPs, the Corps believes that issuing a new NWP to authorize discharges of dredged or fill material into waters of the United States for water reclamation and reuse facilities would be beneficial to the regulated public, especially when these facilities are stand-alone facilities and not attendant features of resident developments, commercial developments, or other activities.

For water reclamation and reuse facilities, the Corps regulates discharges of dredged or fill material into waters of the United States for the construction, expansion, or maintenance of those facilities. In general, the Corps does not have the authority to regulate the operation of these facilities after they are constructed, expanded, or maintained through discharges of dredged or fill material into waters of the United States authorized by this NWP. The Corps does not have the authority to regulate releases of water to recharge or replenish groundwater, to regulate the mixing of water from various sources, or to regulate the movement of water between watersheds. The Corps reminds project proponents that any project including underground injection may be subject to permit requirements of the Underground Injection Control Program, administered under the Safe Drinking Water Act by the U.S. Environmental Protection

Agency or states, territories, or tribes to which it has delegated primacy.

One commenter objected to the proposed 1/2-acre limit for proposed new NWP E. A commenter recommended adding a 300 linear foot limit for losses of stream bed. One commenter said that this NWP should not be limited to non-tidal waters, and it should not prohibit discharges of dredged or fill material into non-tidal wetlands adjacent to tidal waters. This commenter stated that proposed new NWP E should also authorize discharges of dredged or fill material into non-tidal wetlands adjacent to tidal waters as well as tidal waters. One commenter said that mitigation should not be required for activities authorized by this NWP because the NWP authorizes beneficial activities.

The Corps is issuing this new NWP with a 1/2-acre limit to be consistent with other NWPs that may be used to authorizes discharges of dredged or fill material into waters of the United States to construct, expand, or maintain water reclamation and reuse facilities as attendant features of other activities authorized by NWP, such as NWP 29 (residential developments), NWP 39 (commercial and institutional developments), NWP 40 (agricultural activities), and NWP 42 (recreational facilities). Losses of stream bed caused by discharges of dredged or fill material into waters of the United States are also subject to the 1/2-acre limit.

Pre-construction notification is required for all activities authorized by this NWP, and district engineers will evaluate proposed losses of stream bed to determine whether those losses, plus any other losses of waters of the United States caused by discharges of dredged or fill material, will result in no more than minimal individual and cumulative adverse environmental effects, and thus eligible for authorization under this NWP. Because of the PCN requirement and the ability of district and division engineers to modify, suspend, or revoke this NWP when appropriate, the Corps does not believe that it is necessary to impose an additional quantitative limit on this NWP that is specific to losses of stream bed. In geographic areas where there are regional concerns about cumulative losses of stream bed, division engineers can add regional conditions to this NWP to impose smaller acreage limits on losses of stream bed. If, during the review of a PCN for a proposed activity, the district engineer determines the proposed activity will result in more than minimal individual and cumulative adverse environmental effects after considering mitigation proposed by the applicant, he or she will exercise discretionary authority and require an individual permit for the proposed losses of stream bed and any other losses of non-tidal waters and wetlands caused by discharges of dredged or fill material.

The Corps is issuing this NWP with the same scope of applicable waters (*i.e.,* non-tidal waters of the United States, excluding non-tidal wetlands adjacent to tidal waters) as some other NWPs that can be used to authorize discharges of dredged or fill material into waters of the United States for water reclamation and reuse facilities. The scope of applicable waters is consistent with NWPs 29, 39, 40, and 42. This NWP does not authorize discharges of dredged or fill material into tidal waters of the United States and non-tidal wetlands adjacent to tidal waters because discharges into those waters have greater potential to result in adverse environmental effects that are more than minimal, individually and cumulatively. Project proponents that want to discharge dredged or fill material into tidal waters of the United States and non-tidal wetlands adjacent to tidal waters to construct, expand, or maintain water reclamation and reuse facilities can seek DA authorization through the individual permit process, unless a Corps district has issued a regional general permit to authorize those activities. General condition 23 addresses the mitigation requirements for this NWP and other NWPs. District engineers have discretion to require mitigation, including compensatory mitigation, for activities authorized by this NWP when they determine that such mitigation is necessary to ensure that the authorized activities result in no more than minimal individual and cumulative adverse environmental effects.

Proposed new NWP E is issued as NWP 59.

E. Responses to Comments on the Nationwide Permit General Conditions

The NWPs issued in this final rule are subject to the NWP general conditions in the final rule that was published in the January 13, 2021, issue of the **Federal Register** (86 FR 2867–2874). The final rule published in the January 13, 2021, issue of the **Federal Register** includes summaries of comments received on the NWP general conditions for the 2020 Proposal, as well as responses to those comments. See 86 FR 2820–2838 for the comment summaries and responses to comments on the general conditions for the 2021 NWPs.

F. Responses to Comments on the District Engineer's Decision

The NWPs issued in this final rule are subject to the District Engineer's Decision section (section D) in the final rule that was published in the January 13, 2021, issue of the **Federal Register** (86 FR 2874–2875). The final rule published in the January 13, 2021, issue of the **Federal Register** includes summaries of comments received on the NWP general conditions for the 2020 Proposal, as well as responses to those comments. See 86 FR 2838 for the comment summaries and responses to comments on the ''District Engineer's Decision'' section for the 2021 NWPs.

G. Discussion of Proposed Modifications to Section F, Definitions

The NWPs issued in this final rule are subject to the NWP definitions in the final rule that was published in the January 13, 2021, issue of the **Federal Register** (86 FR 2875–2877). The final rule published in the January 13, 2021, issue of the **Federal Register** includes summaries of comments received on the NWP general conditions for the 2020 Proposal, as well as responses to those comments. See 86 FR 2838–2841 for the comment summaries and responses to comments on the definitions for the 2021 NWPs.

III. Compliance With Relevant Statutes

A. National Environmental Policy Act Compliance

The Corps has prepared a decision document for each NWP issued in this final rule. Each decision document contains an environmental assessment (EA) to fulfill the requirements of NEPA. The EA includes the public interest review described in 33 CFR part 320.4. The EA generally discusses the anticipated impacts the NWP will have on the human environment and the Corps' public interest review factors. If a proposed NWP authorizes discharges of dredged or fill material into waters of the United States, the decision document also includes an analysis conducted pursuant to the Clean Water Act Section 404(b)(1), in particular 40 CFR part 230.7. These decision documents evaluate, from a national perspective, the environmental effects of each NWP.

The final decision document for each NWP is available on the internet at: *www.regulations.gov* (docket ID number COE–2020–0002) as Supporting and Related Materials for this final rule. The final decision documents prepared for each NWP fulfill the environmental documentation requirements of NEPA.

Before the 41 NWPs in this final rule go into effect, division engineers will issue supplemental documents to evaluate environmental effects on a regional basis (*e.g.,* a state or Corps district) and to determine whether regional conditions are necessary to ensure that the NWPs will result in no more than minimal individual and cumulative adverse environmental effects on a regional basis. The supplemental documents are prepared by Corps districts, but must be approved and issued by the appropriate division engineer, since the NWP regulations at 33 CFR 330.5(c) state that the division engineer has the authority to modify, suspend, or revoke NWP authorizations in a specific geographic area within his or her division. For some Corps districts, their geographic area of responsibility covers an entire state. For other Corps districts, their geographic area of responsibility may be based on watershed boundaries. For some states, there may be more than one Corps district responsible for implementing the Corps regulatory program, including the NWP program. In states with more than one Corps district, there is a lead Corps district responsible for preparing the supplemental documents for all of the NWPs. The supplemental documents will also discuss regional conditions imposed by division engineers to protect the aquatic environment and other public interest review factors and ensure that any adverse environmental effects resulting from NWP activities in that region will be no more than minimal, individually and cumulatively.

The Corps solicited comments on the draft national decision documents for each proposed NWP, and any comments received were considered when preparing the final decision documents for the NWPs.

Before the final NWPs go into effect, division engineers will issue supplemental documents to evaluate environmental effects on a regional basis (*e.g.,* state or Corps district). The supplemental documents are prepared by Corps districts but must be approved and formally issued by the appropriate division engineer, since the NWP regulations at 33 CFR 330.5(c) state that the division engineer has the authority to modify, suspend, or revoke NWP authorizations for any specific geographic area within his or her division. For some Corps districts, their geographic area of responsibility covers an entire state. For other states, there is more than one Corps district responsible for implementing the Corps Regulatory Program, including the NWP program. In those states, there is a lead Corps district responsible for preparing the supplemental documents for all of the NWPs. The supplemental documents will discuss regional conditions imposed by division engineers to protect the aquatic environment and ensure that any adverse environmental effects resulting from NWP activities in that region will be no more than minimal, individually and cumulatively.

For the NWPs, the assessment of cumulative effects under the Corps' public interest review occurs at three levels: National, regional, and the verification stage. Each national NWP decision document includes a national-scale cumulative effects analysis under the Corps' public interest review. Each supplemental document has a cumulative effects analysis under the Corps' public interest review conducted for a region, which is usually a state or Corps district. When a district engineer issues a verification letter in response to a PCN or a voluntary request for a NWP verification, the district engineer prepares a brief document that explains the decision on whether to issue a verification letter for the proposed NWP activity or exercise discretionary authority to require an individual permit for that proposed activity. The district engineer's document explains whether the proposed NWP activity, after considering permit conditions such as mitigation requirements, will result in no more than minimal individual and cumulative adverse environmental effects.

If the NWP is not suspended or revoked in a state or a Corps district, the supplemental document includes a certification that the use of the NWP in that district, with any applicable regional conditions, will result in no more than minimal cumulative adverse environmental effects.

After the NWPs are issued or reissued and go into effect, district engineers will monitor the use of these NWPs on a regional basis (*e.g.,* within a watershed, county, state, Corps district or other appropriate geographic area), to ensure that the use of a particular NWP is not resulting in more than minimal cumulative adverse environmental effects. The Corps staff that evaluate NWP PCNs that are required by the text of the NWP or by NWP general conditions or regional conditions imposed by division engineers, or voluntarily submitted to the Corps district by project proponents to receive written NWP verifications, often work in a particular geographic area and have an understanding of the activities that have been authorized by NWPs, regional general permits, and individual permits over time, as well as the current environmental setting for that geographic area. If the Corps district staff believe that the use of an NWP in that geographic region may be approaching a threshold above which the cumulative adverse environmental effects for that category of activities may be more than minimal, the district engineer may make a recommendation to the division engineer to modify, suspend, or revoke the NWP authorization in that geographic region in accordance with the procedures in 33 CFR 330.5(c). Alternatively, under the procedures at 33 CFR 330.5(d), the district engineer may also modify, suspend, or revoke NWP authorizations on a case-by-case basis to ensure that the NWP does not authorize activities that result in more than minimal cumulative adverse environmental effects.

Comments on compliance with NEPA for the 2020 Proposal are addressed in the final rule published in the January 13, 2021, issue of the **Federal Register** at 86 FR 2842–2843.

B. Compliance With Section 404(e) of the Clean Water Act

The NWPs are issued in accordance with Section 404(e) of the Clean Water Act and 33 CFR part 330. These NWPs authorize categories of activities that are similar in nature. The ''similar in nature'' requirement does not mean that activities authorized by an NWP must be identical to each other. The Corps believes that the ''categories of activities that are similar in nature'' requirement in Clean Water Act Section 404(e) is to be interpreted broadly, for practical implementation of this general permit program. The Corps has applied this interpretation for many years (see the NWPs issued in 2000 (64 FR 39263–39264 and 65 FR 12821), 2007 (72 FR 11095), 2012 (77 FR 10186), and 2017 (82 FR 1868)).

Nationwide permits, as well as other general permits, are intended to reduce administrative burdens on the Corps and the regulated public while maintaining environmental protection, by efficiently authorizing activities that have no more than minimal adverse environmental effects, consistent with Congressional intent expressed in the 1977 amendments to the Federal Water Pollution Control Act, specifically 33 U.S.C. 1344(e). The NWPs provide incentives for project proponents to minimize impacts to jurisdictional waters and wetlands to qualify for NWP authorization instead of having to apply for individual permits. Keeping the number of NWPs manageable is a key component for making the NWPs

protective of the environment and streamlining the authorization process for those general categories of activities that have no more than minimal individual and cumulative adverse environmental effects.

The various terms and conditions of these NWPs, including the NWP regulations at 33 CFR 330.1(d) and 330.4(e), allow district engineers to exercise discretionary authority to modify, suspend, or revoke NWP authorizations or to require individual permits, and ensure compliance with Section 404(e) of the Clean Water Act. For each NWP that may authorize discharges of dredged or fill material into waters of the United States, the national decision document prepared by Corps Headquarters includes a 404(b)(1) Guidelines analysis. A 404(b)(1) Guidelines analysis is not required when a specific activity is authorized by an NWP (see 40 CFR 230.6(d)).

C. 2020 Revisions to the Definition of ''Waters of the United States'' (i.e., the Navigable Waters Protection Rule)

Corps general permits are not intended to make or imply a conclusion or determination regarding what water bodies are or are not subject to CWA jurisdiction. Instead, a Corps general permit merely states that, if a person complies with all of the terms and conditions of the general permit, that person's proposed discharges of dredged or fill material into the waterbody will be consistent with the CWA, on the ground that any such discharges either (1) are legally authorized under the CWA (to the extent that the waterbody is subject to CWA jurisdiction) or (2) are otherwise consistent with the CWA to the extent that the waterbody is not jurisdictional under the CWA. The Corps acknowledges that some members of the public may seek to comply with the conditions of a general permit even for water bodies that are not jurisdictional or may not be jurisdictional under the CWA. Such practice, though not required, is not unlawful. The Corps is not required to make a formal determination whether a particular wetland or water is subject to jurisdiction under Section 404 of the Clean Water Act or Section 10 of the Rivers and Harbors Act of 1899 before issuing an individual permit or a general permit verification. Many project proponents prefer the time savings that can occur when the Corps issues an individual permit or general permit verification without expending the time and resources needed to make a formal, definitive determination whether those wetlands and waters are in fact jurisdictional and thus regulated under Section 404 of the Clean Water Act and/or Section 10 of the Rivers and Harbors Act of 1899.

On April 21, 2020, the U.S. Environmental Protection Agency (EPA) and the Department of the Army published the Navigable Waters Protection Rule (NWPR) which became effective on June 22, 2020,[3] revising the definition of ''waters of the United States'' (85 FR 22250). Specifically, this final rule revises the Corps' regulations at 33 CFR part 328.3, where the definition of ''waters of the United States'' is located for the purposes of implementing Section 404 of the Clean Water Act.

On January 21, 2021, President Biden signed the E.O. 13990, ''Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis,'' which directs federal agencies to ''immediately review and, as appropriate and consistent with applicable law, take action to address the promulgation of Federal regulations and other actions during the last 4 years that conflict with these important national objectives, and to immediately commence work to confront the climate crisis.'' EPA and the Department of the Army have completed their review of the NWPR and announced in June 2021 their intention to initiate a new rulemaking process that restores the protections in place prior to the 2015 WOTUS implementation, and develops a new rule to establish a durable definition of ''waters of the United States.'' As authorization under Section 404 of the Clean Water Act is only needed when regulated activities occur in WOTUS, any new definition of ''Waters of the United States'' could impact when an NWP may or may not be needed; however, it would not alter the terms and conditions in either this final rule or the NWP rule issued January 13, 2021.

Please note that some of the NWPs could authorize activities that involve the discharge of dredged or fill material into water bodies that are not subject to CWA jurisdiction, or that may not be subject to CWA jurisdiction. For example, a project proponent could proceed with an NWP activity that does not require submission of a PCN to the Corps in a non-jurisdictional water without getting a definitive determination from the Corps that the wetland or waterbody is not a water of the United States and thus not subject to CWA jurisdiction. As another example, if a proposed NWP activity requires pre-construction notification, the district engineer could issue the NWP verification based on the delineation of wetlands, other special aquatic sites, and other waters provided with the PCN in accordance with paragraph (b)(5) of NWP general condition 32, without the Corps making any formal determination as to whether those wetlands, special aquatic sites, and other waters are ''waters of the United States.''

During the pendency of any litigation challenging the Navigable Waters Protection Rule, the NWPs will continue to authorize discharges of dredged or fill material in all water bodies that are subject to CWA jurisdiction, or that may be subject to CWA jurisdiction, at the time those discharges occur. Where a particular waterbody into which a person proposes to discharge dredged or fill material is subject to CWA jurisdiction, compliance with the terms and conditions of one or more NWPs, or an individual permit, will be necessary. A person with legal interest in a parcel (*e.g.,* a permit applicant, landowner, or a lease, easement, or option holder) has the opportunity to request an approved jurisdictional determination from the Corps if that person would like the Corps' formal determination on the jurisdictional status of a water or feature under the CWA.''

D. Compliance With the Endangered Species Act

The NWP regulations at 33 CFR 330.4(f) and NWP general condition 18, endangered species, ensure that all activities authorized by NWPs comply with ESA section 7. Those regulations and general condition 18 require non-federal permittees to submit PCNs for any activity that might affect listed species or designated critical habitat, as well as species proposed for listing and critical habitat proposed for such designation. When the district engineer evaluates a PCN, he or she determines whether the proposed NWP activity may affect listed species or designated critical habitat. The Corps established the ''might affect'' threshold in 33 CFR 330.4(f)(2) and paragraph (c) of general condition 18 because it is more stringent than the ''may affect'' threshold for ESA Section 7 consultation in the U.S. Fish and Wildlife Service's (FWS) and National Marine Fisheries Service's (NMFS) ESA Section 7 consultation regulations at 50 CFR part 402. The word ''might'' is defined as having ''less probability or possibility'' than the word ''may'' (Merriam-Webster's Collegiate

[3] On June 22, 2020, the NWPR became effective except in the State of Colorado due to a federal district court-issued stay in that state. The stay in Colorado has since been lifted so the NWPR is now in effect in all 50 states and U.S. territories. The rule has also been challenged in several other federal district courts.

Dictionary, 10th edition). Since ''might'' has a lower probability of occurring, it is below the threshold (*i.e.,* ''may affect'') that triggers the requirement for ESA Section 7 consultation for a proposed Federal action. As discussed below, each year the Corps conducts thousands of ESA Section 7 consultations with the FWS and NMFS for activities authorized by NWPs. In recent years, an average of more than 10,800 formal, informal, and programmatic ESA Section 7 consultations are conducted each year between the Corps and the FWS and/or NMFS in response to NWP PCNs, including those activities that required PCNs under paragraph (c) of general condition 18 under the ''might affect'' threshold.

If the project proponent is required to submit a PCN and the proposed activity might affect listed species or designated critical habitat, species proposed for listing, or critical habitat proposed for such designation, the activity is not authorized by an NWP until either the district engineer makes a ''no effect'' determination or makes a ''may affect'' determination and completes formal or informal ESA Section 7 consultation. The district engineer may also use a regional programmatic consultation to comply with the requirements of ESA Section 7.

When evaluating a PCN, where necessary and appropriate, the Corps district will either make a ''no effect'' determination or a ''may affect'' determination. If the district engineer makes a ''may affect'' determination, she or he will notify the non-federal project proponent and the activity is not authorized by the NWP until ESA Section 7 consultation has been completed. In making these determinations, the district engineer will apply the definition of ''effects of the action'' in the FWS's and NMFS's ESA consultation regulations at 50 CFR 402.02. If the district engineer initiates ESA Section 7 consultation with the FWS and/or NMFS, that consultation will also consider ESA Section 7 cumulative effects, in accordance with the definition of ''cumulative effects'' at 50 CFR 402.02. If the non-federal project proponent does not comply with 33 CFR 330.4(f)(2) and general condition 18, and does not submit the required PCN, then the activity is not authorized by an NWP. In such situations, it is an unauthorized activity and the Corps district will determine an appropriate course of action under its regulations at 33 CFR part 326 to respond to the unauthorized activity, if and when the Corps learns about that unauthorized activity.

Federal agencies, including state agencies (*e.g.,* certain state Departments of Transportation) to which the Federal Highway Administration has assigned its responsibilities for ESA Section 7 consultation pursuant to 23 U.S.C. 327(a)(2)(B), are required to follow their own procedures for complying with ESA Section 7 (see 33 CFR 330.4(f)(1) and paragraph (b) of general condition 18). This includes circumstances where an NWP activity is part of a larger overall federal project or action. The federal agency's ESA Section 7 compliance covers the NWP activity because it is undertaking the NWP activity and possibly other related activities that are part of a larger overall federal project or action. For those NWPs that require pre-construction notification for proposed activities, the federal permittee is required to provide the district engineer with the appropriate documentation to demonstrate compliance with ESA Section 7. The district engineer will verify that the appropriate documentation has been submitted. If the appropriate documentation has not been submitted, additional ESA Section 7 consultation may be necessary for the proposed activity to fulfill both the federal agency's and the Corps' obligations to comply with ESA Section 7.

The only activities that potentially could be immediately authorized by NWPs, assuming they meet all other applicable NWP conditions, are activities that would have ''no effect'' on listed species or designated critical habitat within the meaning of Section 7 of the ESA and its implementing regulations at 50 CFR part 402. Therefore, the issuance or reissuance of NWPs does not require ESA Section 7 consultation because no activities authorized by any NWPs ''may affect'' listed species or critical habitat without first completing activity-specific ESA Section 7 consultations with the Services, as required by general condition 18 and 33 CFR 330.4(f). Regional programmatic ESA Section 7 consultations may also be used by district engineers to satisfy the requirements of the NWPs in general condition 18 and 33 CFR 330.4(f) if a proposed NWP activity is covered by that regional programmatic consultation.

In the August 27, 2019, issue of the **Federal Register** (84 FR 44976) the FWS and NMFS published a final rule that amended their regulations for interagency cooperation under Section 7 of the ESA. That final rule went into effect on October 28, 2019. With respect to making effects determinations for proposed federal actions, such as activities authorized by NWPs, the FWS and NMFS made two important changes to 50 CFR part 402: (a) Introducing the term ''consequences'' to help define what is an effect under ESA Section 7, and (b) emphasizing that to be considered an ''effect of the action'' under ESA Section 7 consultation, the consequences caused by the action would not occur but for the proposed action and must be reasonably certain to occur (see 84 FR 44977). Further clarification of ''activities that are reasonably certain to occur'' and ''consequences caused by the proposed action'' were provided by the FWS and NMFS in rule text added at 50 CFR 402.17(a) and (b), respectively.

Applying the 2019 amendments to the ESA Section 7 regulations to the NWP program, consequences to listed species and designated critical habitat caused by proposed NWP activities must be reasonably certain to occur. In the preamble to their final rule, the FWS and NMFS stated that for a ''consequence of an activity to be considered reasonably certain to occur, the determination must be based on clear and substantial information'' (see 84 FR 44977). The FWS and NMFS explained that ''clear and substantial'' means that there has to be a firm basis for supporting a conclusion that a consequence of a federal action is reasonably certain to occur. The determination that a consequence is reasonably certain to occur should not be based on speculation or conjecture, and the information used to make that determination should have a ''degree of certitude'' (see 84 FR 44977). The Corps will apply these considerations when evaluating pre-construction notifications for proposed NWP activities.

When the district engineer receives a pre-construction notification for a proposed NWP activity, he or she is responsible for applying the current definition of ''effect of the action'' to the proposed NWP activity and to determine the consequences caused by the proposed action and which activities are reasonably certain to occur. The district engineer determines whether the proposed NWP activity ''may affect'' listed species or designated critical habitat and initiates formal or informal ESA Section 7 consultation, unless she or he determines that the proposed NWP activity will have ''no effect'' on listed species or designated critical habitat. As a general rule, the district engineer documents his or her ''no effect'' determination in writing for every pre-construction notification that the

district engineer receives and responds to.

The NWP program has been structured, through the requirements of NWP general condition 18 and 33 CFR 330.4(f), to focus ESA Section 7 compliance at the activity-specific and regional levels. Each year, an average of more than 10,800 formal, informal, and regional programmatic ESA Section 7 consultations are conducted by Corps districts with the FWS and/or NMFS in response to NWP PCNs for specific NWP activities (see below). Focusing ESA Section 7 compliance at the activity-specific scale and regional programmatic scale is more efficient for the permittees, the Corps, and the FWS and NMFS, than doing so at the national level because of the similarities in ecosystem characteristics and associated listed species and critical habitat within a particular region.

For a proposed NWP activity that may affect listed species or designated critical habitat, a biological opinion with an incidental take statement is needed for the NWP activity to go forward unless the FWS or NMFS issued a written concurrence that the proposed NWP activity is not likely to adversely affect listed species or designated critical habitat. It is through activity-specific ESA Section 7 consultations and regional programmatic ESA Section 7 consultations between the Corps and the FWS and NMFS that effective protection of listed species and their designated critical habitat is achieved.

After applying the current ESA Section 7 regulations at 50 CFR part 402 to the NWP rulemaking process, the Corps continues to believe that the issuance or reissuance of the NWPs has ''no effect'' on listed species or designated critical habitat, and that the ESA Section 7 compliance is most effectively achieved by applying the requirements of general condition 18 and 33 CFR 330.4(f) to specific proposed NWP activities that are identified after the NWPs are issued and go into effect. Compliance with the requirements of ESA Section 7 can also be achieved by district engineers applying appropriate formal or informal regional programmatic ESA Section 7 consultations that have been developed by Corps districts with regional offices of the FWS and NMFS.

Section 7 of the ESA requires each federal agency to ensure, through consultation with the Services, that ''any action authorized, funded, or carried out'' by that agency ''is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species.'' (See 16 U.S.C. 1536(a)(2).) Accordingly, the Services' ESA Section 7 regulations specify that an action agency must ensure that the action ''it authorizes,'' including authorization by permit, does not cause jeopardy or adverse modification. (See 50 CFR 402.01(a) and 402.02). Thus, in assessing application of ESA Section 7 to NWPs issued or reissued by the Corps, the proper focus is on the nature and extent of the specific activities ''authorized'' by the NWPs and the timing of that authorization.

The issuance or reissuance of the NWPs by the Chief of Engineers imposes express limitations on activities authorized by these NWPs. These limitations are imposed by the NWP terms and conditions, including the general conditions that apply to all NWPs regardless of whether pre-construction notification is required by a specific NWP. With respect to listed species and critical habitat, general condition 18 expressly prohibits any activity ''which 'may affect' a listed species or designated critical habitat, unless ESA Section 7 consultation addressing the effects of the proposed activity has been completed.'' General condition 18 also states that if an activity ''might affect'' a listed species or designated critical habitat (or a species proposed for listing or critical habitat proposed for such designation), a non-federal applicant must submit a PCN and ''shall not begin work on the activity until notified by the district engineer that the requirements of the ESA have been satisfied and that the activity is authorized.'' In addition, 33 CFR 330.4(f)(2) imposes a PCN requirement for proposed NWP activities by non-federal permittees where listed species (or species proposed for listing) or critical habitat might be affected or are in the vicinity of the proposed NWP activity. Section 330.4(f)(2) also prohibits those permittees from beginning the NWP activity until notified by the district engineer that the requirements of the ESA have been satisfied and that the activity is authorized. Permit applicants that are federal agencies must and will follow their own requirements for complying with the ESA (see 33 CFR 330.4(f)(1)).

Thus, because no NWP can or does authorize an activity that may affect a listed species or critical habitat absent an activity-specific ESA Section 7 consultation or applicable regional programmatic ESA Section 7 consultation, and because any activity that may affect a listed species or critical habitat must undergo an activity-specific consultation or be in compliance with a regional programmatic ESA Section 7 consultation before the district engineer can verify that the activity is authorized by an NWP, the issuance or reissuance of NWPs has ''no effect'' on listed species or critical habitat. Accordingly, the action being ''authorized'' by the Corps (*i.e.,* the issuance or re-issuance of the NWPs themselves) has no effect on listed species or critical habitat.

To help ensure protection of listed species and critical habitat, general condition 18 and 33 CFR 330.4(f) establish a more stringent threshold than the threshold set forth in the Services' ESA Section 7 regulations for initiation of ESA Section 7 consultation. Specifically, while ESA Section 7 consultation must be initiated for any activity that ''may affect'' listed species or critical habitat, for non-federal permittees general condition 18 require submission of a PCN to the Corps if ''any listed species (or species proposed for listing) or designated critical habitat might be affected or is in the vicinity of the activity, or if the activity is located in designated critical habitat'' or critical habitat proposed for such designation, and prohibits work until ''notified by the district engineer that the requirements of the ESA have been satisfied and that the activity is authorized.'' (See paragraph (c) of general condition 18.) The PCN must ''include the name(s) of the endangered or threatened species (or species proposed for listing) that might be affected by the proposed work or that utilize the designated critical habitat (or critical habitat proposed for such designation) that might be affected by the proposed work.'' (See paragraph (b)(7) of the ''Pre-Construction Notification'' general condition.) Paragraph (g) of general condition 18 notes that information on the location of listed species and their critical habitat can be obtained from the Services directly or from their websites.

General condition 18 makes it clear to project proponents that an NWP does not authorize the ''take'' of an endangered or threatened species. Paragraph (e) of general condition 18 also states that a separate authorization (*e.g.,* an ESA Section 10 permit or a biological opinion with an ''incidental take statement'') is required to take a listed species. In addition, paragraph (a) of general condition 18 states that no activity is authorized by an NWP which is likely to ''directly or indirectly jeopardize the continued existence of a threatened or endangered species or a species proposed for such designation'' or ''which will directly or indirectly

destroy or adversely modify the critical habitat of such species.'' Such activities would require district engineers to exercise their discretionary authority and subject the proposed activity to the individual permit review process, because an activity that would jeopardize the continued existence of a listed species, or a species proposed for listing, or that would destroy or adversely modify the critical habitat of such species would not result in no more than minimal adverse environmental effects and thus cannot be authorized by an NWP.

The Corps' NWP regulations at 33 CFR 330.1(c) state that an ''activity is authorized under an NWP only if that activity and the permittee satisfy all of the NWP's terms and conditions.'' Thus, if a project proponent moves forward with an activity that ''might affect'' an ESA listed species without complying with the PCN or other requirements of general condition 18, the activity is not authorized under the CWA. In this case, the project proponent could be subject to enforcement action and penalties under the CWA. In addition, if the unauthorized activity results in a ''take'' of listed species as defined by the ESA and its implementing regulations, then he or she could be subject to penalties, enforcement actions, and other actions by the FWS or NMFS under Section 11 of the ESA.

For listed species (and species proposed for listing) under the jurisdiction of the FWS, information on listed species that may be present in the vicinity of a proposed activity is available through the Information Planning and Consultation (IPaC) system,[4] an on-line project planning tool developed and maintained by the FWS.

During the process for developing regional conditions, Corps districts collaborate with FWS and/or NMFS regional or field offices to identify regional conditions that can provide additional assurance of compliance with general condition 18 and 33 CFR 330.4(f)(2). Such regional conditions can add PCN requirements to one or more NWPs in areas inhabited by listed species or where designated critical habitat occurs. Regional conditions can also be used to establish time-of-year restrictions when no NWP activity can take place to ensure that individuals of listed species are not adversely affected by such activities. Corps districts will continue to consider through regional collaborations and consultations, local initiatives, or other cooperative efforts additional information and measures to ensure protection of listed species and critical habitat, the requirements established by general condition 18 (which apply to all uses of all NWPs), and other provisions of the Corps regulations ensure full compliance with ESA Section 7.

Corps district office personnel meet with local representatives of the FWS and NMFS to establish or modify existing procedures, where necessary, to ensure that the Corps has the latest information regarding the existence and location of any threatened or endangered species or their critical habitat, including species proposed for listing or critical habitat proposed for such designation. Corps districts can also establish, through local procedures or other means, additional safeguards that ensure compliance with the ESA. Through formal ESA Section 7 consultation, or through other coordination with the FWS and/or the NMFS, as appropriate, the Corps establishes procedures to ensure that NWP activities will not jeopardize any threatened and endangered species or result in the destruction or adverse modification of designated critical habitat. Such procedures may result in the development of regional conditions added to the NWP by the division engineer, or in activity-specific conditions to be added to an NWP authorization by the district engineer.

The Corps has prepared a biological assessment for this rulemaking action. The biological assessment concludes that the issuance or reissuance of NWPs has ''no effect'' on listed species and designated critical habitat and does not require ESA Section 7 consultation. This conclusion was reached because no activities authorized by any NWPs ''may affect'' listed species or critical habitat without first completing activity-specific ESA Section 7 consultations with the Services, as required by general condition 18 and 33 CFR 330.4(f).

Based on the fact that NWP issuance or reissuance of the NWPs is contingent upon any proposed NWP activity that ''may affect'' listed species or critical habitat undergoing an activity-specific or regional programmatic ESA Section 7 consultation, there is no requirement that the Corps undertake consultation for the NWP program. The national programmatic consultations conducted in the past for the NWP program were voluntary consultations despite the inclusion of procedures to ensure consultation under ESA Section 7 for proposed NWP activities that may affect listed species or designated critical habitat. Regional programmatic consultations can be conducted voluntarily by Corps districts and regional or local offices of the FWS and/or NMFS to tailor regional conditions and procedures to ensure the ''might affect'' threshold is implemented consistently and effectively.

Examples of regional programmatic consultations currently in effect, with the applicable Service the Corps consulted with, include: The Standard Local Operating Procedures for Endangered Species in Mississippi (2017—FWS); the Endangered Species Act Section 7 Programmatic Biological Opinion and Magnuson-Stevens Fishery Conservation and Management Act Essential Fish Habitat Consultation for Tidal Area Restoration Authorized, Funded, or Implemented by the Corps of Engineers, Federal Emergency Management Agency, and Federal Highways Administration, in Oregon and the Lower Columbia River (NMFS—2018); the U.S. Army Corps of Engineers Jacksonville District's Programmatic Biological Opinion (JAXBO) (NMFS—2017); Missouri Bat Programmatic Informal Consultation Framework (FWS—2019); Revised Programmatic Biological/Conference Opinion for bridge and culvert repair and replacement projects affecting the Dwarf Wedgemussel, Tar River Spinymussel, Yellow Lance and Atlantic Pigtoe. Programmatic Conference Opinion (PCO) for Bridge and Culvert Replacement/Repairs/Rehabilitations in Eastern North Carolina, NCDOT Divisions 1–8 (FWS—2018); and the Corps and NOAA Fisheries Greater Atlantic Regional Fisheries Office (GARFO) Not Likely to Adversely Affect Program Programmatic Consultation (NMFS—2017).

The programmatic ESA Section 7 consultations that the Corps conducted for the 2007 and 2012 NWPs were voluntary consultations. The voluntary programmatic consultation conducted with the NMFS for the 2012 NWPs resulted in a biological opinion issued on February 15, 2012, which was replaced by a new biological opinion issued on November 24, 2014. A new biological opinion was issued by NMFS after the proposed action was modified and triggered re-initiation of that programmatic consultation. The programmatic consultation on the 2012 NWPs with the FWS did not result in a biological opinion. For the 2017 NWPs, the Corps did not request a national programmatic consultation.

In the Corps Regulatory Program's automated information system (ORM), the Corps collects data on all individual permit applications, all NWP PCNs, all voluntary requests for NWP verifications where the NWP or general conditions do not require PCNs, and all

[4] *https://ecos.fws.gov/ipac/.*

verifications of activities authorized by regional general permits. For all written authorizations issued by the Corps, the collected data include authorized impacts and required compensatory mitigation, as well as information on all consultations conducted under ESA Section 7. Every year, the Corps evaluates approximately 35,000 NWP PCNs and requests for NWP verifications for activities that do not require PCNs, and provides written verifications for those activities when district engineers determine those activities result in no more than minimal adverse environmental effects. During the evaluation process, district engineers assess potential impacts to listed species and critical habitat and conduct ESA Section 7 consultations whenever they determine proposed NWP activities ''may affect'' listed species or critical habitat. District engineers will exercise discretionary authority and require individual permits when proposed NWP activities will result in more than minimal adverse environmental effects.

Each year, the Corps conducts thousands of ESA Section 7 consultations with the FWS and NMFS for activities authorized by NWPs. These ESA Section 7 consultations are tracked in ORM. In FY 2018 (October 1, 2017 to September 30, 2018), Corps districts conducted 640 formal consultations and 3,048 informal consultations under ESA Section 7 for NWP PCNs. During that time period, the Corps also used regional programmatic consultations for 7,148 NWP PCNs to comply with ESA Section 7. Therefore, each year an average of more than 10,800 formal, informal, and programmatic ESA Section 7 consultations are conducted between the Corps and the FWS and/or NMFS in response to NWP PCNs, including those activities that required PCNs under paragraph (c) of general condition 18. For a linear project authorized by NWPs 12, 14, 57, or 58 where the district engineer determines that one or more crossings of waters of the United States that require Corps authorization ''may affect'' listed species or designated critical habitat, the district engineer initiates a single ESA Section 7 consultation with the FWS and/or NMFS for all of those crossings that he or she determines ''may affect'' listed species or designate critical habitat. The number of ESA Section 7 consultations provided above represents the number of NWP PCNs that required some form of ESA Section 7 consultation, not the number of single and complete projects authorized by an NWP that may be included in a single PCN. A single NWP PCN may include more than one single and complete project, especially if it is for a linear project such as a utility line or road with multiple separate and distant crossings of jurisdictional waters and wetlands from its point of origin to its terminal point.

During the process for reissuing the NWPs, Corps districts coordinated with regional and field offices of the FWS and NMFS to discuss whether new or modified regional conditions should be imposed on the NWPs to improve implementation of the ''might effect'' threshold and improve protection of listed species and designated critical habitat and ensure that the NWPs only authorize activities with no more than minimal individual and cumulative adverse environmental effects. Regional conditions must comply with the Corps' regulations at 33 CFR 325.4 for adding permit conditions to DA authorizations. The Corps decides whether suggested regional conditions identified during this coordination are appropriate for the NWPs. During this coordination, other tools, such as additional regional programmatic consultations or standard local operating procedures, might be developed by the Corps, FWS, and NMFS to facilitate compliance with the ESA while streamlining the process for authorizing activities under the NWPs. ESA Section 7 consultation on regional conditions occurs only when a Corps districts makes a ''may affect'' determination and initiates formal or informal ESA Section 7 consultation with the FWS and/or NMFS, depending on the species that may be affected. Otherwise, the Corps district coordinates the regional conditions with the FWS and/or NMFS. Regional conditions, standard local operating procedures, and regional programmatic consultations developed by the Corps, FWS, and NMFS are important tools for protecting listed species and critical habitat and helping to tailor the NWP program to address specific species, their habitats, and the stressors that affect those species.

Comments on compliance with the ESA for the 2020 Proposal are addressed in the final rule published in the January 13, 2021, issue of the **Federal Register** at 86 FR 2848–2849.

E. Compliance With the Essential Fish Habitat Provisions of the Magnuson-Stevens Fishery Conservation and Management Act

The NWP Program's compliance with the essential fish habitat (EFH) consultation requirements of the Magnuson-Stevens Fishery Conservation and Management Act will be achieved through EFH consultations between Corps districts and NMFS regional offices. This approach continues the EFH Conservation Recommendations provided by NMFS Headquarters to Corps Headquarters in 1999 for the NWP program. Corps districts that have EFH designated within their geographic areas of responsibility will coordinate with NMFS regional offices, to the extent necessary, to develop NWP regional conditions that conserve EFH and are consistent with the NMFS regional EFH Conservation Recommendations. Corps districts will conduct consultations in accordance with the EFH consultation regulations at 50 CFR 600.920.

Comments on compliance with the essential fish habitat (EFH) consultation requirements of the Magnuson-Stevens Fishery Conservation and Management Act for the 2020 Proposal are addressed in the final rule published in the January 13, 2021, issue of the **Federal Register** at 86 FR 2849.

F. Compliance With Section 106 of the National Historic Preservation Act

The NWP regulations at 33 CFR 330.4(g) and the ''Historic Properties'' general condition (general condition 20), ensure that all activities authorized by NWPs comply with Section 106 of the NHPA. The ''Historic Properties'' general condition requires non-federal permittees to submit PCNs for any activity that might have the potential to cause effects to any historic properties listed on, determined to be eligible for listing on, or potentially eligible for listing on the National Register of Historic Places, including previously unidentified properties. The Corps then evaluates the PCN and makes an effect determination for the proposed NWP activity for the purposes of NHPA Section 106. The Corps established the ''might have the potential to cause effects'' threshold in paragraph (c) of the ''Historic Properties'' general condition to require PCNs for those activities so that the district engineer can evaluate the proposed NWP activity and determine whether it has no potential to cause effects to historic properties or whether it has potential to cause effects to historic properties and thus require NHPA Section 106 consultation.

If the project proponent is required to submit a PCN and the proposed activity might have the potential to cause effects to historic properties, the activity is not authorized by an NWP until either the Corps district makes a ''no potential to cause effects'' determination or completes NHPA Section 106 consultation.

When evaluating a PCN, the Corps will either make a ''no potential to cause effects'' determination or a ''no historic properties affected,'' ''no adverse effect,'' or ''adverse effect'' determination. If the Corps makes a ''no historic properties affected,'' ''no adverse effect,'' or ''adverse effect'' determination, the district engineer will notify the non-federal applicant and the activity is not authorized by an NWP until NHPA Section 106 consultation has been completed. If the non-federal project proponent does not comply with the ''Historic Properties'' general condition, and does not submit the required PCN, then the activity is not authorized by an NWP. In such situations, it is an unauthorized activity and the Corps district will determine an appropriate course of action to respond to the unauthorized activity.

The only activities that are immediately authorized by NWPs are ''no potential to cause effect'' activities under Section 106 of the NHPA, its implementing regulations at 36 CFR part 800, and the Corps' ''Revised Interim Guidance for Implementing Appendix C of 33 CFR part 325 with the Revised Advisory Council on Historic Preservation Regulations at 36 CFR part 800,'' dated April 25, 2005, and amended on January 31, 2007. Therefore, the issuance or reissuance of NWPs does not require NHPA Section 106 consultation because no activities that might have the potential to cause effects to historic properties can be authorized by an NWP without first completing activity-specific NHPA Section 106 consultations, as required by the ''Historic Properties'' general condition. Programmatic agreements (see 36 CFR 800.14(b)) may also be used to satisfy the requirements of the NWPs in the ''Historic Properties'' general condition if a proposed NWP activity is covered by that programmatic agreement.

NHPA Section 106 requires a federal agency that has authority to license or permit any undertaking, to take into account the effect of the undertaking on any district, site, building, structure, or object that is included in or eligible for inclusion in the National Register, prior to issuing a license or permit. The head of any such Federal agency shall afford the Advisory Council on Historic Preservation a reasonable opportunity to comment on the undertaking. Thus, in assessing application of NHPA Section 106 to NWPs issued or reissued by the Corps, the proper focus is on the nature and extent of the specific activities ''authorized'' by the NWPs and the timing of that authorization.

The issuance or reissuance of the NWPs by the Chief of Engineers imposes express limitations on activities authorized by those NWPs. These limitations are imposed by the NWP terms and conditions, including the general conditions that apply to all NWPs regardless of whether pre-construction notification is required. With respect to historic properties, the ''Historic Properties'' general condition expressly prohibits any activity that ''may have the potential to cause effects to properties listed, or eligible for listing, in the National Register of Historic Places,'' until the requirements of NHPA Section 106 have been satisfied. The ''Historic Properties'' general condition also states that if an activity ''might have the potential to cause effects'' to any historic properties, a non-federal applicant must submit a PCN and ''shall not begin the activity until notified by the district engineer either that the activity has no potential to cause effects to historic properties or that consultation under Section 106 of the NHPA has been completed.'' Permit applicants that are Federal agencies should follow their own requirements for complying with Section 106 of the NHPA (see 33 CFR 330.4(g)(1) and paragraph (b) of the ''Historic Properties'' general condition).

Thus, because no NWP can or does authorize an activity that may have the potential to cause effects to historic properties, and because any activity that may have the potential to cause effects to historic properties must undergo an activity-specific NHPA Section 106 consultation (unless that activity is covered under a programmatic agreement) before the district engineer can verify that the activity is authorized by an NWP, the issuance or reissuance of NWPs has ''no potential to cause effects'' on historic properties. Accordingly, the action being ''authorized'' by the Corps, which is the issuance or re-issuance of the NWPs by Corps Headquarters, has no potential to cause effects on historic properties.

To help ensure protection of historic properties, the ''Historic Properties'' general condition establishes a higher threshold than the threshold set forth in the Advisory Council's NHPA Section 106 regulations for initiation of section 106 consultation. Specifically, while NHPA Section 106 consultation must be initiated for any activity that ''has the potential to cause effects to'' historic properties, for non-federal permittees the ''Historic Properties'' general condition requires submission of a PCN to the Corps if ''the NWP activity might have the potential to cause effects to any historic properties listed on, determined to be eligible for listing on, or potentially eligible for listing on the National Register of Historic Places, including previously unidentified properties.'' The ''Historic Properties'' general condition also prohibits the proponent from conducting the NWP activity ''until notified by the district engineer either that the activity has no potential to cause effects to historic properties or that consultation under Section 106 of the NHPA has been completed.'' (See paragraph (d) of the ''Historic Properties'' general condition.) The PCN must ''state which historic property might have the potential to be affected by the proposed activity or include a vicinity map indicating the location of the historic property.'' (See paragraph (b)(8) of the ''Pre-Construction Notification'' general condition.)

During the process for developing regional conditions, Corps districts can coordinate or consult with State Historic Preservation Officers, Tribal Historic Preservation Officers, and tribes to identify regional conditions that can provide additional assurance of compliance with the ''Historic Properties'' general condition and 33 CFR 330.4(g)(2) for NWP activities undertaken by non-federal permittees. Such regional conditions can add PCN requirements to one or more NWPs where historic properties occur. Corps districts will continue to consider through regional consultations, local initiatives, or other cooperative efforts and additional information and measures to ensure protection of historic properties, the requirements established by the ''Historic Properties'' general condition (which apply to all uses of all NWPs), and other provisions of the Corps regulations and guidance ensure full compliance with NHPA Section 106.

Based on the fact that NWP issuance or reissuance has no potential to cause effects on historic properties and that any activity that ''has the potential to cause effects'' to historic properties will undergo activity-specific NHPA Section 106 consultation, there is no requirement that the Corps undertake programmatic consultation for the NWP program. Regional programmatic agreements can be established by Corps districts and State Historic Preservation Officers and/or Tribal Historic Preservation Officers to comply with the requirements of Section 106 of the NHPA.

Comments on compliance with Section 106 of the NHPA for the 2020 Proposal are addressed in the final rule published in the January 13, 2021, issue of the **Federal Register** at 86 FR 2851.

G. Section 401 of the Clean Water Act

A water quality certification (WQC) issued by a state, authorized tribe, or EPA, or a waiver thereof, is required by section 401 of the Clean Water Act, for an activity authorized by an NWP which may result in a discharge from a point source into waters of the United States. Water quality certifications may be granted without conditions, granted with conditions, denied, or waived for specific NWPs. The water quality certification process for the 2020 Proposal was described in the preamble to the September 15, 2020, proposed rule at 85 FR 57362—57363. A summary of comments received on the water quality certification process for the 2020 Proposal, and the Corps' responses to those comments, are provided in the final rule that was published in the **Federal Register** on January 13, 2021, at 86 FR 2851—2853.

Nationwide permits numbered 15, 16, 17, 18, 25, 30, 34, 41, 46, 49, and 59 would authorize activities that may result in discharges and therefore water quality certification is required for those NWPs. Nationwide permits numbered 3, 4, 5, 6, 7, 13, 14, 19, 20, 22, 23, 27, 31, 32, 33, 36, 37, 38, 45, 53, and 54 would authorize various activities, some of which may result in a discharge and require water quality certification, and others which may not. Nationwide permits numbered 1, 2, 8, 9, 10, 11, 24, 28, and 35 do not require water quality certification because they would authorize activities which, in the opinion of the Corps, could not reasonably be expected to result in a discharge into waters of the United States. In the case of NWP 8, it authorizes only activities seaward of the territorial seas.

In October 2020, Corps districts requested WQC from certifying authorities for the proposed issuance of the NWPs, including the 41 NWPs being issued in this final rule. Many certifying authorities requested an extension to the 60-day reasonable period of time established by the Corps to review and certify the proposed NWPs (see 86 FR 2744, 2852). Commenters noted various reasons for such extension requests, including that certifying authorities could not comply with the reasonable period of time due to public participation requirements and the need for more time to review in light of recent changes to the EPA's regulation for Section 401 of the Clean Water Act and the issuance of the final Navigable Waters Protection Rule. In light of concerns noted by commenters, the Corps extended the reasonable period of time for certification of the 41 NWPs in this final rule. Corps districts sent letters to certifying authorities notifying them of the extended reasonable period of time for the 41 NWPs in this final rule. For the extended reasonable period of time, Corps districts gave the certifying authorities the opportunity to take different courses of action on the certification requests for the proposed issuance of these 41 NWPs. Certifying authorities also had the option to take no further action during the extended reasonable period of time. If a certifying authority took no further action during the extended reasonable period of time, the Corps would consider the certifying authority's prior action on the certification request to be their final position on WQC for the issuance of these 41 NWPs: that is to issue with or without conditions, deny, or waive WQC for those 41 NWPs.

Under EPA's 401 regulations, a ''[f]ederal agency may extend the reasonable period of time at the request of a certifying authority or a project proponent'' so long as the reasonable period of time does not exceed one year from receipt of the certification request.'' (See 40 CFR 121.6(d).) In the October 2020 certification requests, the Corps established the reasonable period of time to be 60 days. Although the original reasonable period of time of 60 days has passed, EPA's 401 regulations do not prohibit federal agencies from granting certifying authorities more time to take action on certification requests, as long as no more than one year has passed since the original certification request was submitted to a certifying authority. Additionally, the Corps' NWP regulations do not prohibit reopening the reasonable period of time as long as the one-year limit in Section 401 of the Clean Water Act is not exceeded. Therefore, in response to concerns expressed by certifying authorities and various commenters, the Corps extended the reasonable period of time to give certifying authorities the one-year maximum in the statute to act on the certification requests on the remaining 41 NWPs. To be clear, this extension of the reasonable period of time does not constitute the submittal of new certification requests by Corps districts to certifying authorities. If certifying authorities need additional time, the Corps will work with certifying authorities as necessary, as long as the statutory one-year limit is not exceeded. Furthermore, because the Corps is simply extending the reasonable period of time (and not re-requesting certification) certifying authorities were not required to reinitiate the certification process.

Although certifying authorities previously submitted certifications on the 41 NWPs, the Corps finds that submission of new or revised certifications during this extended reasonable period of time would not be ''modifications'' of the earlier certifications or otherwise inconsistent with 40 CFR 121.6(e). Instead, any new or revised certifications submitted during the extended reasonable period of time will be deemed to supersede the earlier certifications or other actions (such as denials or waivers) that certifying authorities may have taken during the original reasonable period of time. *See also* Memorandum from Radhika Fox, Assistant Administrator, Office of Water, and Jaime Pinkham, Acting Assistant Secretary of the Army (Civil Works), *Clean Water Act Section 401 Certification Implementation,* at 6–7 (August 19, 2021), available at *https://www.epa.gov/system/files/documents/2021-08/8-19-21-joint-epa-army-memo-on-cwa-401-implementation_508.pdf* (providing that ''EPA's 2020 Rule does not limit certifying authorities from issuing an updated certification within the reasonable period of time when this is authorized by the federal permitting agency. . . . In EPA's view, this outcome does not change if the new or revised certification is issued during an extended reasonable period of time.'') Certifying authorities that want to retain their prior certification decisions can confirm their prior positions affirmatively by sending confirmation to the Corps district prior the expiration of the extended reasonable period of time, If a certifying authority chooses not to respond to the Corps district during the extended reasonable period of time, the previous certification decisions will govern in the absence of an updated certification, affirmative confirmation, or other action, such as a denial or waiver.

EPA was available to provide technical assistance to the Corps and certifying authorities pursuant to 40 CFR 121.16 during this extended reasonable period of time.

Consistent with EPA's 401 regulations at 40 CFR part 121, certifying authorities may take one of four actions on a certification request: To issue with or without conditions, deny, or waive WQC for the issuance of the NWPs. If a certifying authority issues water quality certifications with conditions for the issuance of these NWPs, district engineers reviews the conditions in those water quality certifications to determine whether they comply with the requirements in 40 CFR 121.7(d). If the district engineer determines that any condition in the water quality

certification for the issuance of the NWPs does not comply with the requirements of 40 CFR 121.7(d), and is waived pursuant to 40 CFR 121.9(d), the district engineer will notify the certifying authority and the EPA Administrator in accordance with 40 CFR 121.9(c). The conditions in the water quality certification for the issuance of the NWP that comply with the requirements of 40 CFR 121.7(d) and are not waived become conditions of the NWP authorization in accordance with Section 401(d) of the Clean Water Act.

The Corps' regulations for reviewing WQCs issued for the issuance of the NWPs are located at 33 CFR 330.4(c)(2). If, prior to the issuance or reissuance of NWPs, a certifying authority issues a WQC for the issuance of an NWP, and that WQC includes conditions, the division engineer will make those conditions regional conditions of the NWP for activities which may result in a discharge into waters of United States in the geographic area covered by that WQC unless the division engineer determines that those conditions do not comply with the provisions of 33 CFR 325.4. If the district engineer determines that the conditions in a WQC provided for the issuance of an NWP do not comply with 33 CFR 325.4 the Corps will decline to rely on the WQC issued for the issuance of the NWP. In practice, this means the Corps will consider that decision to be a denial of the certification. In such cases, the proposed discharges are not authorized by that NWP and the Corps will require project proponents to obtain WQCs for individual discharges authorized by that NWP.

If a certifying agency denies WQC for the issuance of an NWP, then the proposed discharges are not authorized by that NWP unless and until a project proponent obtains WQC for the specific discharge from the certifying authority, or a waiver of WQC occurs.

After division engineers have approved the final regional conditions for the 41 NWPs published in this final rule, Corps districts will issue public notices announcing the final regional conditions for the 41 NWPs and the status of water quality certifications and Coastal Zone Management Act (CZMA) consistency concurrences for those final NWPs. The Corps will post copies of these district public notices in the *www.regulations.gov* docket for this rulemaking action (docket number COE–2020–0002).

Further discussion of comments on compliance with Section 401 of the Clean Water Act for the 2020 Proposal are addressed in the final rule published in the January 13, 2021, issue of the **Federal Register** at 86 FR 2852–2853.

H. Section 307 of the Coastal Zone Management Act (CZMA)

Any state with a federally-approved CZMA program must concur with the Corps' determination that activities authorized by NWPs which are within, or will have reasonably foreseeable effects on any land or water uses or natural resources of, the state's coastal zone, are consistent with the CZMA program to the maximum extent practicable. Coastal Zone Management Act consistency concurrences may be issued without conditions, issued with conditions, or denied for specific NWPs.

Prior to the issuance of the 16 NWPs, states made their decisions on whether to concur with or object to the Corps' CZMA consistency determination for the issuance of the NWPs. If a state issued a concurrence with conditions for the issuance of these NWPs, district engineers reviewed the conditions in those consistency concurrences to determine whether they comply with the Corps' regulations for permit conditions at 33 CFR 325.4. If a state objected to the Corps' CZMA consistency determination for the issuance of an NWP, then the activity is not authorized by that NWP unless and until a project proponent obtains a consistency concurrence from the state or a presumption of concurrence occurs.

The Corps' CZMA consistency determination only applied to NWP authorizations for activities that are within, or affect, any land, water uses or natural resources of a state's coastal zone. A state's coastal zone management plan may identify geographic areas in federal waters on the outer continental shelf, where activities that require federal permits conducted in those areas require consistency certification from the state because they affect any coastal use or resource. In its coastal zone management plan, the state may include an outer continental shelf plan. An outer continental shelf plan is a plan for ''the exploration or development of, or production from, any area which has been leased under the Outer Continental Shelf Lands Act'' and regulations issued under that Act (see 15 CFR 930.73). Activities requiring federal permits that are not identified in the state's outer continental shelf plan are considered unlisted activities. If the state wants to review an unlisted activity under the CZMA, then it must notify the applicant and the federal permitting agency that it intends to review the proposed activity. Nationwide permit authorizations for activities that are not within or would not affect a state's coastal zone do not require the Corps' CZMA consistency determinations and thus are not contingent on a State's concurrence with the Corps' consistency determinations.

If a state objects to the Corps' CZMA consistency determination for an NWP, then the affected activities are not authorized by an NWP within that state until a project proponent obtains an individual CZMA consistency concurrence, or sufficient time (*i.e.,* six months) passes after requesting a CZMA consistency concurrence for the applicant to make a presumption of consistency, as provided in 33 CFR 330.4(d)(6). However, when applicants request NWP verifications for activities that require individual consistency concurrences, and the Corps determines that those activities meet the terms and conditions of the NWP, in accordance with 33 CFR 330.6(a)(3)(iii) the Corps will issue provisional NWP verification letters. The provisional verification letter will contain general and regional conditions as well as any activity-specific conditions the Corps determines are necessary for the NWP authorization. The Corps will notify the applicant that he or she must obtain an activity-specific CZMA consistency concurrence or a presumption of concurrence before he or she is authorized to start work in waters of the United States. That is, NWP authorization will be contingent upon obtaining the necessary CZMA consistency concurrence from the state, or a presumption of concurrence. Anyone wanting to perform such activities where pre-construction notification to the Corps is not required has an affirmative responsibility to present a CZMA consistency determination to the appropriate state agency for concurrence. Upon concurrence with such CZMA consistency determinations by the state, the activity would be authorized by the NWP. This requirement is provided at 33 CFR 330.4(d).

Comments on compliance with the Coastal Zone Management Act for the 2020 Proposal are addressed in the final rule published in the January 13, 2021, issue of the **Federal Register** at 86 FR 2854.

IV. Economic Impact

The NWPs are expected to increase the number of activities eligible for NWP authorization, and reduce the number of activities that require individual permits. The Corps estimates that the NWPs in this final rule will authorize 52 activities each year that would have otherwise required individual permits. For the combination

of this final rule with the final rule issued in January 2021, the Corps estimates that the 2021 NWPs will authorize 261 activities each year that would have otherwise required individual permits. While applying for a NWP may entail some burden (namely, in the form of a PCN, when applicable), by authorizing more activities by NWP, this proposal will reduce net burden for the regulated public. Specifically, increasing the number of activities that can be authorized by NWPs is expected to decrease compliance costs for permit applicants since, as discussed below, the compliance costs for obtaining NWP authorization are less than the compliance costs for obtaining individual permits. In addition, the NWPs can incentivize some project proponents to design their projects in such a way that they would qualify for a NWP thereby reducing impacts to jurisdictional waters and wetlands. In FY2018, the average time to receive an NWP verification was 45 days from the date the Corps district receives a complete PCN, compared to 264 days to receive a standard individual permit after receipt of a complete permit application (see table 1.2 of the regulatory impact analysis for this final rule, which is available in the *www.regulations.gov* docket (docket number COE–2020–0002)).

As discussed in the Regulatory Impact Analysis for this rule, the Corps estimates that a permit applicant's compliance cost for obtaining NWP authorization in 2019$ ranges from $4,412 to $14,705 (Institute for Water Resources (2001),[5] adjusted for inflation using the GDP deflator approach). The Corps estimates that a permit applicant's compliance costs for obtaining an individual permit for a proposed activity impacting up to 3 acres of wetland ranges from $17,646 to $35,293 in 2019$. Considering how the proposed NWPs will increase the number of activities authorized by an NWP each year, the Corps estimates that the 41 final NWPs, when compared with the 2017 NWPs, will decrease compliance costs for the regulated public by approximately $1.1 million (low end estimate) to $3.2 million per year (high end estimate). The Corps estimates that the 41 final NWPs in this final rule plus the 16 NWPs issued in the January 13, 2021, final rule, when compared with the 2017 NWPs, will decrease compliance costs for the regulated public by approximately $5.4 million (low end estimate) to $16.2 million per year (high end estimate). The Corps invited comment on the assumptions and methodology used to calculate the compliance costs and burden in general associated with the NWP and received no comments.

Nationwide permit(s)	Changes	Anticipated impacts
• NWP 14	Add "driveways" to examples of activities authorized by this NWP.	Increase number of activities authorized by NWP; decrease number of activities requiring individual permits.
• NWP 27	Add coral restoration and relocation to the list of examples of authorized activities. Add "releases of sediment from reservoirs to maintain sediment transport continuity to restore downstream habitats" to the list of examples of authorized activities.	Increase number of activities authorized by NWP; decrease number of activities requiring individual permits.
• NWP 41	Add irrigation ditches	Increased number of activities authorized by NWP; decreased number of activities requiring individual permits.
• NWP 53	Change definition of low-head dam	Slight increase in number of low-head dams removed each year.
• NWP 59	Issued new NWP to authorize discharges of dredged or fill material into waters of the United States to construct, expand, and maintain water reclamation and reuse facilities.	Increased number of activities authorized by NWP; decreased number of activities requiring individual permits.

Comments on the potential economic impacts of the 2020 Proposal, and the Corps' responses to those comments, are provided in the final rule published in the January 13, 2021, issue of the **Federal Register** at 86 FR 2855–2856.

V. Administrative Requirements

Plain Language

In compliance with the principles in the President's Memorandum of June 1, 1998, (63 FR 31885, June 10, 1998) regarding plain language, this preamble is written using plain language. In writing this final rule, the Corps used the active voice, short sentences, and common everyday terms except for necessary technical terms.

Paperwork Reduction Act

The paperwork burden associated with the NWP relates exclusively to the preparation of the PCN. While different NWPs require that different information be included in a PCN, the Corps estimates that a PCN takes, on average, 11 hours to complete. The 41 NWPs issued in this final rule would decrease the total paperwork burden associated with this program because the Corps estimates that under this final rule 47 more PCNs would be required each year. This increase is due to the number of activities that would be authorized under the 41 2021 NWPs that previously required individual permits. The paperwork burden associated with the 41 final NWPs is expected to increase by approximately 1,517 hours per year from 198,397 hours to 199,914 hours.

The following table summarizes the projected changes in paperwork burden from the 40 2017 NWPs to the 41 NWPs issued in this final rule.

	Number of NWP PCNs per year	Number of NWP activities not requiring PCNs per year	Estimated changes in NWP PCNs per year	Estimated changes in number of authorized NWP activities	Estimated changes in number of standard individual permits per year
40 2017 NWPs	18,127	29,265	.....	.....	.....

[5] Institute for Water Resources (IWR). 2001. Cost analysis for the 2000 issuance and modification of nationwide permits. Institute for Water Resources (Alexandria, VA). 29 pp. plus appendices.

	Number of NWP PCNs per year	Number of NWP activities not requiring PCNs per year	Estimated changes in NWP PCNs per year	Estimated changes in number of authorized NWP activities	Estimated changes in number of standard individual permits per year
41 2021 NWPs	18,164	29,280	+37	+52	−52

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 Office of Management and Budget (OMB) control number. For the Corps Regulatory Program under Section 10 of the Rivers and Harbors Act of 1899, Section 404 of the Clean Water Act, and Section 103 of the Marine Protection, Research and Sanctuaries Act of 1972, the current OMB approval number for information collection requirements is maintained by the Corps of Engineers (OMB approval number 0710–0003).

Executive Order 12866

This action is a significant regulatory action under Executive Order 12866 (58 FR 51735, October 4, 1993) that was submitted to the Office of Management and Budget (OMB) for review.

Executive Order 13132

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires the Corps 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.'' The issuance and modification of NWPs does not have federalism implications. The Corps does not believe that the final NWPs will 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. These NWPs will not impose any additional substantive obligations on state or local governments. Therefore, Executive Order 13132 does not apply to these NWPs.

Regulatory Flexibility Act, as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 et seq.

The Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice-and-comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of the issuance and modification of NWPs on small entities, a small entity is defined as: (1) A small business based on Small Business Administration size standards; (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; or (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

The statutes under which the Corps issues, reissues, or modifies NWPs are Section 404(e) of the Clean Water Act (33 U.S.C. 1344(e)) and Section 10 of the Rivers and Harbors Act of 1899 (33 U.S.C. 403). Under section 404, DA permits are required for discharges of dredged or fill material into waters of the United States. Under section 10, DA permits are required for any structures or other work that affect the course, location, or condition of navigable waters of the United States. Small entities proposing to discharge dredged or fill material into waters of the United States and/or install structures or conduct work in navigable waters of the United States must obtain DA permits to conduct those activities, unless a particular activity is exempt from those permit requirements. Individual permits and general permits can be issued by the Corps to satisfy the permit requirements of these two statutes. Nationwide permits are a form of general permit issued by the Chief of Engineers.

Nationwide permits automatically expire and become null and void if they are not modified or reissued within five years of their effective date (see 33 CFR 330.6(b)). Furthermore, Section 404(e) of the Clean Water Act states that general permits, including NWPs, can be issued for no more than five years. If the 40 2017 NWPs that were not included in the final rule published in the January 13, 2021, issue of the **Federal Register** are not modified or reissued, they will expire on March 18, 2022, and small entities and other project proponents would be required to obtain alternative forms of DA permits (*i.e.,* standard permits, letters of permission, or regional general permits) for activities involving discharges of dredged or fill material into waters of the United States or structures or work in navigable waters of the United States. Regional general permits that authorize similar activities as the NWPs may be available in some geographic areas, but small entities conducting regulated activities outside those geographic areas would have to obtain individual permits for activities that require DA permits.

When compared with the compliance costs for individual permits, most of the terms and conditions of the NWPs are expected to result in decreases in the costs of complying with the permit requirements of sections 10 and 404. The anticipated decrease in compliance cost results from the lower cost of obtaining NWP authorization instead of standard permits. Unlike standard permits, NWPs authorize activities without the requirement for public notice and comment on each proposed activity.

Another requirement of Section 404(e) of the Clean Water Act is that general permits, including NWPs, authorize only those activities that result in no more than minimal adverse environmental effects, individually and cumulatively. The terms and conditions of the NWPs, such as acreage limits and the mitigation measures in some of the NWP general conditions, are imposed to ensure that the NWPs authorize only those activities that result in no more than minimal adverse effects on the aquatic environment and other public interest review factors.

After considering the economic impacts of the NWPs on small entities, I certify that this action will not have a significant impact on a substantial number of small entities. Small entities may obtain required DA authorizations through the NWPs, in cases where there are applicable NWPs authorizing those activities and the proposed work will result in only minimal adverse effects on the aquatic environment and other public interest review factors. The terms and conditions of the revised NWPs will not impose substantially higher costs on small entities than those of the existing NWPs. If an NWP is not available to

authorize a particular activity, then another form of DA authorization, such as an individual permit or a regional general permit authorization, must be secured. However, as noted above, the Corps estimates an increase in the number of activities than can be authorized through NWPs, because the Corps made some modifications to the NWPs to authorize additional activities. Because those activities required authorization through other forms of DA authorization (*e.g.,* individual permits or regional general permits) the Corps expects a concurrent decrease in the numbers of individual permit and regional general permit authorizations required for these activities.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments, and the private sector. Under Section 202 of the UMRA, the agencies generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''federal mandates'' that may result in expenditures to state, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating a rule for which a written statement is needed, Section 205 of the UMRA generally requires the agencies to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows an agency to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the agency publishes with the final rule an explanation why that alternative was not adopted. Before an agency establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed, under Section 203 of the UMRA, a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of regulatory proposals with significant federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

The Corps has determined that the NWPs do not contain a federal mandate that may result in expenditures of $100 million or more for state, local, and tribal governments, in the aggregate, or the private sector in any one year. The NWPs are generally consistent with current agency practice, do not impose new substantive requirements and therefore do not contain a federal mandate that may result in expenditures of $100 million or more for state, local, and tribal governments, in the aggregate, or the private sector in any one year. Therefore, this final rule is not subject to the requirements of Sections 202 and 205 of the UMRA. For the same reasons, the Corps has determined that the NWPs contain no regulatory requirements that might significantly or uniquely affect small governments. Therefore, the issuance and modification of NWPs is not subject to the requirements of Section 203 of UMRA.

Executive Order 13045

Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that we have reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, we must evaluate the environmental health or safety effects of the proposed rule on children and explain why the regulation is preferable to other potentially effective and reasonably feasible alternatives.

The NWPs are not subject to this Executive Order because they are not economically significant as defined in Executive Order 12866. In addition, the proposed NWPs do not concern an environmental health or safety risk that the Corps has reason to believe may have a disproportionate effect on children.

Executive Order 13175

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 6, 2000), requires agencies to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' The phrase ''policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Tribes, on the relationship between the federal government and the Tribes, or on the distribution of power and responsibilities between the federal government and Tribes.''

The issuance of these NWPs is generally consistent with current agency practice and will not have substantial direct effects on tribal governments, on the relationship between the federal government and the tribes, or on the distribution of power and responsibilities between the federal government and tribes. Therefore, Executive Order 13175 does not apply to this final rule. However, in the spirit of Executive Order 13175, the Corps specifically requested comments from tribal officials on the proposed rule. Their comments were fully considered during the preparation of this final rule. Each Corps district conducted government-to-government consultation with tribes, to identify regional conditions, other local NWP modifications to protect aquatic resources of interest to tribes, and coordination procedures with tribes, as part of the Corps' responsibility to protect tribal trust resources and fulfill its tribal trust responsibilities.

Comments on compliance of the 2020 Proposal with E.O. 13175, and the Corps' responses to those comments, are provided in the final rule published in the January 13, 2021, issue of the **Federal Register** at 86 FR 2858–2859.

Environmental Documentation

A decision document has been prepared for each of the 41 NWPs being issued in this final rule. Each decision document includes an environmental assessment and public interest review determination. If an NWP authorizes discharges of dredged or fill material into waters of the United States, the decision document includes a 404(b)(1) Guidelines analysis. These decision documents are available at: *www.regulations.gov* (docket ID number COE–2020–0002). They are also available by contacting Headquarters, U.S. Army Corps of Engineers, Operations and Regulatory Community of Practice, 441 G Street NW, Washington, DC 20314–1000.

Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, 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. The Corps will submit a report containing the final 41 NWPs and other required information to

the U.S. Senate, the U.S. House of Representatives, and the Government Accountability Office. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. The 41 NWPs are not a ''major rule'' as defined by 5 U.S.C. 804(2), because they are not likely to result in (1) an annual effect on the economy of $100,000,000 or more; (2) a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; or (3) 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.

Executive Order 12898

Executive Order 12898 requires that, to the greatest extent practicable and permitted by law, each federal agency must make achieving environmental justice part of its mission. Executive Order 12898 provides that each federal agency conduct its programs, policies, and activities that substantially affect human health or the environment in a manner that ensures that such programs, policies, and activities do not have the effect of excluding persons (including populations) from participation in, denying persons (including populations) the benefits of, or subjecting persons (including populations) to discrimination under such programs, policies, and activities because of their race, color, or national origin.

In response to the 2020 Proposal, the Corps received one comment concerning environmental justice. One commenter said that the proposed NWPs would diminish protections for subsistence hunting and fishing rights for tribes, and that the proposed rule does not comply with E.O. 12898. This commenter concluded that the final rule should not be issued.

Activities authorized by the NWPs must comply with general condition 17, tribal rights. General condition 17 states that no NWP activity or its operation may impair reserved tribal rights, including, but not limited to, reserved water rights and treaty fishing and hunting rights. For the 2021 NWPs, Corps districts conducted consultation or coordination with tribes to identify regional conditions that protect reserved tribal rights and to develop coordination procedures for specific NWP activities to ensure that those activities do not impair reserved tribal rights.

The NWPs are not expected to have any discriminatory effect or disproportionate negative impact on any community or group, and therefore are not expected to cause any disproportionately high and adverse impacts to minority or low-income communities. The NWPs can only be used to authorize activities that require DA authorization and result in no more than minimal individual and cumulative adverse environmental effects. The NWPs may be used by people who live in communities with environmental justice interests and undertake activities that require DA authorization. The NWPs are available in all communities to authorize discharges of dredged or fill material into waters of the United States and/or structures and work in navigable waters of the United States that result in no more than minimal individual and cumulative adverse environmental effects, as long as those NWPs have not been suspended or revoke by a division engineer on a regional basis. Those NWP activities may help provide goods and services (*e.g.,* housing, energy, food production, internet access) that benefit members of communities with environmental justice interests.

Executive Order 13211

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy and has not otherwise been designated by the OIRA Administrator as a significant energy action.

VI. References

A complete list of all references cited in this document is available on the internet at *http://www.regulations.gov* in docket number COE–2020–0002 or upon request from the U.S. Army Corps of Engineers (see **FOR FURTHER INFORMATION CONTACT**).

Authority

The Corps is reissuing 40 existing NWPs and issuing one new NWP under the authority of Section 404(e) of the Clean Water Act (33 U.S.C. 1344(e)) and Section 10 of the Rivers and Harbors Act of 1899 (33 U.S.C. 401 *et seq.*).

William H. Graham, Jr.,

Major General, U.S. Army, Deputy Commanding General for Civil and Emergency Operations.

A. Index of Nationwide Permits Issued in This Final Rule

1. Aids to Navigation
2. Structures in Artificial Canals
3. Maintenance
4. Fish and Wildlife Harvesting, Enhancement, and Attraction Devices and Activities
5. Scientific Measurement Devices
6. Survey Activities
7. Outfall Structures and Associated Intake Structures
8. Oil and Gas Structures on the Outer Continental Shelf
9. Structures in Fleeting and Anchorage Areas
10. Mooring Buoys
11. Temporary Recreational Structures
13. Bank Stabilization
14. Linear Transportation Projects
15. U.S. Coast Guard Approved Bridges
16. Return Water From Upland Contained Disposal Areas
17. Hydropower Projects
18. Minor Discharges
19. Minor Dredging
20. Response Operations for Oil or Hazardous Substances
22. Removal of Vessels
23. Approved Categorical Exclusions
24. Indian Tribe or State Administered Section 404 Programs
25. Structural Discharges
27. Aquatic Habitat Restoration, Establishment, and Enhancement Activities
28. Modifications of Existing Marinas
30. Moist Soil Management for Wildlife
31. Maintenance of Existing Flood Control Facilities
32. Completed Enforcement Actions
33. Temporary Construction, Access, and Dewatering
34. Cranberry Production Activities
35. Maintenance Dredging of Existing Basins
36. Boat Ramps
37. Emergency Watershed Protection and Rehabilitation
38. Cleanup of Hazardous and Toxic Waste
41. Reshaping Existing Drainage Ditches
45. Repair of Uplands Damaged by Discrete Events
46. Discharges in Ditches
49. Coal Remining Activities
53. Removal of Low-Head Dams
54. Living Shorelines
59. Water Reclamation and Reuse Facilities

B. Nationwide Permits

1. *Aids to Navigation.* The placement of aids to navigation and regulatory markers that are approved by and installed in accordance with the requirements of the U.S. Coast Guard (see 33 CFR, chapter I, subchapter C, part 66). (Authority: Section 10 of the Rivers and Harbors Act of 1899 (Section 10)).

2. *Structures in Artificial Canals.* Structures constructed in artificial canals within principally residential developments where the connection of the canal to a navigable water of the United States has been previously

authorized (see 33 CFR 322.5(g)). (Authority: Section 10).

3. *Maintenance.* (a) The repair, rehabilitation, or replacement of any previously authorized, currently serviceable structure or fill, or of any currently serviceable structure or fill authorized by 33 CFR 330.3, provided that the structure or fill is not to be put to uses differing from those uses specified or contemplated for it in the original permit or the most recently authorized modification. Minor deviations in the structure's configuration or filled area, including those due to changes in materials, construction techniques, requirements of other regulatory agencies, or current construction codes or safety standards that are necessary to make the repair, rehabilitation, or replacement are authorized. This NWP also authorizes the removal of previously authorized structures or fills. Any stream channel modification is limited to the minimum necessary for the repair, rehabilitation, or replacement of the structure or fill; such modifications, including the removal of material from the stream channel, must be immediately adjacent to the project. This NWP also authorizes the removal of accumulated sediment and debris within, and in the immediate vicinity of, the structure or fill. This NWP also authorizes the repair, rehabilitation, or replacement of those structures or fills destroyed or damaged by storms, floods, fire or other discrete events, provided the repair, rehabilitation, or replacement is commenced, or is under contract to commence, within two years of the date of their destruction or damage. In cases of catastrophic events, such as hurricanes or tornadoes, this two-year limit may be waived by the district engineer, provided the permittee can demonstrate funding, contract, or other similar delays.

(b) This NWP also authorizes the removal of accumulated sediments and debris outside the immediate vicinity of existing structures (*e.g.,* bridges, culverted road crossings, water intake structures, etc.). The removal of sediment is limited to the minimum necessary to restore the waterway in the vicinity of the structure to the approximate dimensions that existed when the structure was built, but cannot extend farther than 200 feet in any direction from the structure. This 200 foot limit does not apply to maintenance dredging to remove accumulated sediments blocking or restricting outfall and intake structures or to maintenance dredging to remove accumulated sediments from canals associated with outfall and intake structures. All dredged or excavated materials must be deposited and retained in an area that has no waters of the United States unless otherwise specifically approved by the district engineer under separate authorization.

(c) This NWP also authorizes temporary structures, fills, and work, including the use of temporary mats, necessary to conduct the maintenance activity. Appropriate measures must be taken to maintain normal downstream flows and minimize flooding to the maximum extent practicable, when temporary structures, work, and discharges of dredged or fill material, including cofferdams, are necessary for construction activities, access fills, or dewatering of construction sites. Temporary fills must consist of materials, and be placed in a manner, that will not be eroded by expected high flows. After conducting the maintenance activity, temporary fills must be removed in their entirety and the affected areas returned to pre-construction elevations. The areas affected by temporary fills must be revegetated, as appropriate.

(d) This NWP does not authorize maintenance dredging for the primary purpose of navigation. This NWP does not authorize beach restoration. This NWP does not authorize new stream channelization or stream relocation projects.

Notification: For activities authorized by paragraph (b) of this NWP, the permittee must submit a pre-construction notification to the district engineer prior to commencing the activity (see general condition 32). The pre-construction notification must include information regarding the original design capacities and configurations of the outfalls, intakes, small impoundments, and canals. (Authorities: Section 10 of the Rivers and Harbors Act of 1899 and Section 404 of the Clean Water Act (Sections 10 and 404)).

Note: This NWP authorizes the repair, rehabilitation, or replacement of any previously authorized structure or fill that does not qualify for the Clean Water Act Section 404(f) exemption for maintenance.

4. *Fish and Wildlife Harvesting, Enhancement, and Attraction Devices and Activities.* Fish and wildlife harvesting devices and activities such as pound nets, crab traps, crab dredging, eel pots, lobster traps, duck blinds, and clam and oyster digging, fish aggregating devices, and small fish attraction devices such as open water fish concentrators (sea kites, etc.). This NWP does not authorize artificial reefs or impoundments and semi-impoundments of waters of the United States for the culture or holding of motile species such as lobster, or the use of covered oyster trays or clam racks. (Authorities: Sections 10 and 404).

5. *Scientific Measurement Devices.* Devices, whose purpose is to measure and record scientific data, such as staff gages, tide and current gages, meteorological stations, water recording and biological observation devices, water quality testing and improvement devices, and similar structures. Small weirs and flumes constructed primarily to record water quantity and velocity are also authorized provided the discharge of dredged or fill material is limited to 25 cubic yards. Upon completion of the use of the device to measure and record scientific data, the measuring device and any other structures or fills associated with that device (*e.g.,* foundations, anchors, buoys, lines, etc.) must be removed to the maximum extent practicable and the site restored to pre-construction elevations. (Authorities: Sections 10 and 404).

6. *Survey Activities.* Survey activities, such as core sampling, seismic exploratory operations, plugging of seismic shot holes and other exploratory-type bore holes, exploratory trenching, soil surveys, sampling, sample plots or transects for wetland delineations, and historic resources surveys. For the purposes of this NWP, the term ''exploratory trenching'' means mechanical land clearing of the upper soil profile to expose bedrock or substrate, for the purpose of mapping or sampling the exposed material. The area in which the exploratory trench is dug must be restored to its pre-construction elevation upon completion of the work and must not drain a water of the United States. In wetlands, the top 6 to 12 inches of the trench should normally be backfilled with topsoil from the trench. This NWP authorizes the construction of temporary pads, provided the discharge of dredged or fill material does not exceed 1/10-acre in waters of the U.S. Discharges of dredged or fill material and structures associated with the recovery of historic resources are not authorized by this NWP. Drilling and the discharge of excavated material from test wells for oil and gas exploration are not authorized by this NWP; the plugging of such wells is authorized. Fill placed for roads and other similar activities is not authorized by this NWP. The NWP does not authorize any permanent structures. The discharge of drilling mud and cuttings may require a permit under Section 402 of the Clean Water Act. (Authorities: Sections 10 and 404).

7. *Outfall Structures and Associated Intake Structures.* Activities related to the construction or modification of outfall structures and associated intake structures, where the effluent from the outfall is authorized, conditionally authorized, or specifically exempted by, or otherwise in compliance with regulations issued under the National Pollutant Discharge Elimination System Program (Section 402 of the Clean Water Act). The construction of intake structures is not authorized by this NWP unless they are directly associated with an authorized outfall structure.

Notification: The permittee must submit a pre-construction notification to the district engineer prior to commencing the activity. (See general condition 32.) (Authorities: Sections 10 and 404).

8. *Oil and Gas Structures on the Outer Continental Shelf.* Structures for the exploration, production, and transportation of oil, gas, and minerals on the outer continental shelf within areas leased for such purposes by the Department of the Interior, Bureau of Ocean Energy Management. Such structures shall not be placed within the limits of any designated shipping safety fairway or traffic separation scheme, except temporary anchors that comply with the fairway regulations in 33 CFR 322.5(l). The district engineer will review such proposals to ensure compliance with the provisions of the fairway regulations in 33 CFR 322.5(l). Any Corps review under this NWP will be limited to the effects on navigation and national security in accordance with 33 CFR 322.5(f), as well as 33 CFR 322.5(l) and 33 CFR part 334. Such structures will not be placed in established danger zones or restricted areas as designated in 33 CFR part 334, nor will such structures be permitted in EPA or Corps-designated dredged material disposal areas.

Notification: The permittee must submit a pre-construction notification to the district engineer prior to commencing the activity. (See general condition 32.) (Authority: Section 10).

9. *Structures in Fleeting and Anchorage Areas.* Structures, buoys, floats, and other devices placed within anchorage or fleeting areas to facilitate moorage of vessels where such areas have been established for that purpose. (Authority: Section 10).

10. *Mooring Buoys.* Non-commercial, single-boat, mooring buoys. (Authority: Section 10).

11. *Temporary Recreational Structures.* Temporary buoys, markers, small floating docks, and similar structures placed for recreational use during specific events such as water skiing competitions and boat races or seasonal use, provided that such structures are removed within 30 days after use has been discontinued. At Corps of Engineers reservoirs, the reservoir managers must approve each buoy or marker individually. (Authority: Section 10).

13. *Bank Stabilization.* Bank stabilization activities necessary for erosion control or prevention, such as vegetative stabilization, bioengineering, sills, rip rap, revetment, gabion baskets, stream barbs, and bulkheads, or combinations of bank stabilization techniques, provided the activity meets all of the following criteria:

(a) No material is placed in excess of the minimum needed for erosion protection;

(b) The activity is no more than 500 feet in length along the bank, unless the district engineer waives this criterion by making a written determination concluding that the discharge of dredged or fill material will result in no more than minimal adverse environmental effects (an exception is for bulkheads—the district engineer cannot issue a waiver for a bulkhead that is greater than 1,000 feet in length along the bank);

(c) The activity will not exceed an average of one cubic yard per running foot, as measured along the length of the treated bank, below the plane of the ordinary high water mark or the high tide line, unless the district engineer waives this criterion by making a written determination concluding that the discharge of dredged or fill material will result in no more than minimal adverse environmental effects;

(d) The activity does not involve discharges of dredged or fill material into special aquatic sites, unless the district engineer waives this criterion by making a written determination concluding that the discharge of dredged or fill material will result in no more than minimal adverse environmental effects;

(e) No material is of a type, or is placed in any location, or in any manner, that will impair surface water flow into or out of any waters of the United States;

(f) No material is placed in a manner that will be eroded by normal or expected high flows (properly anchored native trees and treetops may be used in low energy areas);

(g) Native plants appropriate for current site conditions, including salinity, must be used for bioengineering or vegetative bank stabilization;

(h) The activity is not a stream channelization activity; and

(i) The activity must be properly maintained, which may require repairing it after severe storms or erosion events. This NWP authorizes those maintenance and repair activities if they require authorization.

This NWP also authorizes temporary structures, fills, and work, including the use of temporary mats, necessary to construct the bank stabilization activity. Appropriate measures must be taken to maintain normal downstream flows and minimize flooding to the maximum extent practicable, when temporary structures, work, and discharges of dredged or fill material, including cofferdams, are necessary for construction activities, access fills, or dewatering of construction sites. Temporary fills must consist of materials, and be placed in a manner, that will not be eroded by expected high flows. After construction, temporary fills must be removed in their entirety and the affected areas returned to pre-construction elevations. The areas affected by temporary fills must be revegetated, as appropriate.

Notification: The permittee must submit a pre-construction notification to the district engineer prior to commencing the activity if the bank stabilization activity: (1) Involves discharges of dredged or fill material into special aquatic sites; or (2) is in excess of 500 feet in length; or (3) will involve the discharge of dredged or fill material of greater than an average of one cubic yard per running foot as measured along the length of the treated bank, below the plane of the ordinary high water mark or the high tide line. (See general condition 32.) (Authorities: Sections 10 and 404)

Note: In coastal waters and the Great Lakes, living shorelines may be an appropriate option for bank stabilization, and may be authorized by NWP 54.

14. *Linear Transportation Projects.* Activities required for crossings of waters of the United States associated with the construction, expansion, modification, or improvement of linear transportation projects (*e.g.,* roads, highways, railways, trails, driveways, airport runways, and taxiways) in waters of the United States. For linear transportation projects in non-tidal waters, the discharge of dredged or fill material cannot cause the loss of greater than ½-acre of waters of the United States. For linear transportation projects in tidal waters, the discharge of dredged or fill material cannot cause the loss of greater than ⅓-acre of waters of the United States. Any stream channel modification, including bank stabilization, is limited to the minimum

necessary to construct or protect the linear transportation project; such modifications must be in the immediate vicinity of the project.

This NWP also authorizes temporary structures, fills, and work, including the use of temporary mats, necessary to construct the linear transportation project. Appropriate measures must be taken to maintain normal downstream flows and minimize flooding to the maximum extent practicable, when temporary structures, work, and discharges of dredged or fill material, including cofferdams, are necessary for construction activities, access fills, or dewatering of construction sites. Temporary fills must consist of materials, and be placed in a manner, that will not be eroded by expected high flows. Temporary fills must be removed in their entirety and the affected areas returned to pre-construction elevations. The areas affected by temporary fills must be revegetated, as appropriate.

This NWP cannot be used to authorize non-linear features commonly associated with transportation projects, such as vehicle maintenance or storage buildings, parking lots, train stations, or aircraft hangars.

Notification: The permittee must submit a pre-construction notification to the district engineer prior to commencing the activity if: (1) The loss of waters of the United States exceeds 1/10 acre; or (2) there is a discharge of dredged or fill material in a special aquatic site, including wetlands. (See general condition 32.) (Authorities: Sections 10 and 404).

Note 1: For linear transportation projects crossing a single waterbody more than one time at separate and distant locations, or multiple waterbodies at separate and distant locations, each crossing is considered a single and complete project for purposes of NWP authorization. Linear transportation projects must comply with 33 CFR 330.6(d).

Note 2: Some discharges of dredged or fill material for the construction of farm roads or forest roads, or temporary roads for moving mining equipment, may qualify for an exemption under Section 404(f) of the Clean Water Act (see 33 CFR 323.4).

Note 3: For NWP 14 activities that require pre-construction notification, the PCN must include any other NWP(s), regional general permit(s), or individual permit(s) used or intended to be used to authorize any part of the proposed project or any related activity, including other separate and distant crossings that require Department of the Army authorization but do not require pre-construction notification (see paragraph (b)(4) of general condition 32). The district engineer will evaluate the PCN in accordance with Section D, ''District Engineer's Decision.'' The district engineer may require mitigation to ensure that the authorized activity results in no more than minimal individual and cumulative adverse environmental effects (see general condition 23).

15. *U.S. Coast Guard Approved Bridges.* Discharges of dredged or fill material incidental to the construction of a bridge across navigable waters of the United States, including cofferdams, abutments, foundation seals, piers, and temporary construction and access fills, provided the construction of the bridge structure has been authorized by the U.S. Coast Guard under Section 9 of the Rivers and Harbors Act of 1899 or other applicable laws. Causeways and approach fills are not included in this NWP and will require a separate Clean Water Act Section 404 permit. (Authority: Section 404 of the Clean Water Act (Section 404)).

16. *Return Water From Upland Contained Disposal Areas.* Return water from an upland contained dredged material disposal area. The return water from a contained disposal area is administratively defined as a discharge of dredged material by 33 CFR 323.2(d), even though the disposal itself occurs in an area that has no waters of the United States and does not require a section 404 permit. This NWP satisfies the technical requirement for a section 404 permit for the return water where the quality of the return water is controlled by the state through the Clean Water Act Section 401 certification procedures. The dredging activity may require a section 404 permit (33 CFR 323.2(d)), and will require a section 10 permit if located in navigable waters of the United States. (Authority: Section 404).

17. *Hydropower Projects.* Discharges of dredged or fill material associated with hydropower projects having: (a) Less than 10,000 kW of total generating capacity at existing reservoirs, where the project, including the fill, is licensed by the Federal Energy Regulatory Commission (FERC) under the Federal Power Act of 1920, as amended; or (b) a licensing exemption granted by the FERC pursuant to Section 408 of the Energy Security Act of 1980 (16 U.S.C. 2705 and 2708) and Section 30 of the Federal Power Act, as amended.

Notification: The permittee must submit a pre-construction notification to the district engineer prior to commencing the activity. (See general condition 32.) (Authority: Section 404)

18. *Minor Discharges.* Minor discharges of dredged or fill material into all waters of the United States, provided the activity meets all of the following criteria:

(a) The quantity of discharged dredged or fill material and the volume of area excavated do not exceed 25 cubic yards below the plane of the ordinary high water mark or the high tide line;

(b) The discharge of dredged or fill material will not cause the loss of more than 1/10 acre of waters of the United States; and

(c) The discharge of dredged or fill material is not placed for the purpose of a stream diversion.

Notification: The permittee must submit a pre-construction notification to the district engineer prior to commencing the activity if: (1) The discharge of dredged or fill material or the volume of area excavated exceeds 10 cubic yards below the plane of the ordinary high water mark or the high tide line, or (2) the discharge of dredged or fill material is in a special aquatic site, including wetlands. (See general condition 32.) (Authorities: Sections 10 and 404).

19. *Minor Dredging.* Dredging of no more than 25 cubic yards below the plane of the ordinary high water mark or the mean high water mark from navigable waters of the United States (*i.e.,* section 10 waters). This NWP does not authorize the dredging or degradation through siltation of coral reefs, sites that support submerged aquatic vegetation (including sites where submerged aquatic vegetation is documented to exist but may not be present in a given year), anadromous fish spawning areas, or wetlands, or the connection of canals or other artificial waterways to navigable waters of the United States (see 33 CFR 322.5(g)). All dredged material must be deposited and retained in an area that has no waters of the United States unless otherwise specifically approved by the district engineer under separate authorization. (Authorities: Sections 10 and 404).

20. *Response Operations for Oil or Hazardous Substances.* Activities conducted in response to a discharge or release of oil or hazardous substances that are subject to the National Oil and Hazardous Substances Pollution Contingency Plan (40 CFR part 300) including containment, cleanup, and mitigation efforts, provided that the activities are done under either: (1) The Spill Control and Countermeasure Plan required by 40 CFR 112.3; (2) the direction or oversight of the federal on-scene coordinator designated by 40 CFR part 300; or (3) any approved existing state, regional or local contingency plan provided that the Regional Response

Team (if one exists in the area) concurs with the proposed response efforts. This NWP also authorizes activities required for the cleanup of oil releases in waters of the United States from electrical equipment that are governed by EPA's polychlorinated biphenyl spill response regulations at 40 CFR part 761. This NWP also authorizes the use of temporary structures and fills in waters of the U.S. for spill response training exercises. (Authorities: Sections 10 and 404).

22. *Removal of Vessels.* Temporary structures or minor discharges of dredged or fill material required for the removal of wrecked, abandoned, or disabled vessels, or the removal of man-made obstructions to navigation. This NWP does not authorize maintenance dredging, shoal removal, or riverbank snagging.

Notification: The permittee must submit a pre-construction notification to the district engineer prior to commencing the activity if: (1) The vessel is listed or eligible for listing in the National Register of Historic Places; or (2) the activity is conducted in a special aquatic site, including coral reefs and wetlands. (See general condition 32.) If the vessel is listed or eligible for listing in the National Register of Historic Places, the permittee cannot commence the activity until informed by the district engineer that compliance with the ''Historic Properties'' general condition is completed. (Authorities: Sections 10 and 404).

Note 1: Intentional ocean disposal of vessels at sea requires a permit from the U.S. EPA under the Marine Protection, Research and Sanctuaries Act, which specifies that ocean disposal should only be pursued when land-based alternatives are not available. If a Department of the Army permit is required for vessel disposal in waters of the United States, separate authorization will be required.

Note 2: Compliance with general condition 18, Endangered Species, and general condition 20, Historic Properties, is required for all NWPs. The concern with historic properties is emphasized in the notification requirements for this NWP because of the possibility that shipwrecks may be historic properties.

23. *Approved Categorical Exclusions.* Activities undertaken, assisted, authorized, regulated, funded, or financed, in whole or in part, by another Federal agency or department where:

(a) That agency or department has determined, pursuant to the Council on Environmental Quality's implementing regulations for the National Environmental Policy Act (40 CFR part 1500 *et seq.*), that the activity is categorically excluded from the requirement to prepare an environmental impact statement or environmental assessment analysis, because it is included within a category of actions which neither individually nor cumulatively have a significant effect on the human environment; and

(b) The Office of the Chief of Engineers (Attn: CECW–CO) has concurred with that agency's or department's determination that the activity is categorically excluded and approved the activity for authorization under NWP 23.

The Office of the Chief of Engineers may require additional conditions, including pre-construction notification, for authorization of an agency's categorical exclusions under this NWP.

Notification: Certain categorical exclusions approved for authorization under this NWP require the permittee to submit a pre-construction notification to the district engineer prior to commencing the activity (see general condition 32). The activities that require pre-construction notification are listed in the appropriate Regulatory Guidance Letter(s). (Authorities: Sections 10 and 404).

Note: The agency or department may submit an application for an activity believed to be categorically excluded to the Office of the Chief of Engineers (Attn: CECW–CO). Prior to approval for authorization under this NWP of any agency's activity, the Office of the Chief of Engineers will solicit public comment. As of the date of issuance of this NWP, agencies with approved categorical exclusions are: the Bureau of Reclamation, Federal Highway Administration, and U.S. Coast Guard. Activities approved for authorization under this NWP as of the date of this notice are found in Corps Regulatory Guidance Letter 05–07. Any future approved categorical exclusions will be announced in Regulatory Guidance Letters and posted on this same website.

24. *Indian Tribe or State Administered Section 404 Programs.* Any activity permitted by a state or Indian Tribe administering its own section 404 permit program pursuant to 33 U.S.C. 1344(g)–(l) is permitted pursuant to Section 10 of the Rivers and Harbors Act of 1899. (Authority: Section 10).

Note 1: As of the date of the promulgation of this NWP, only Florida, New Jersey and Michigan administer their own Clean Water Act Section 404 permit programs.

Note 2: Those activities that do not involve an Indian Tribe or State Clean Water Act Section 404 permit are not included in this NWP, but certain structures will be exempted by Section 154 of Public Law 94–587, 90 Stat. 2917 (33 U.S.C. 591) (see 33 CFR 322.4(b)).

25. *Structural Discharges.* Discharges of dredged or fill material such as concrete, sand, rock, etc., into tightly sealed forms or cells where the material will be used as a structural member for standard pile supported structures, such as bridges, transmission line footings, and walkways, or for general navigation, such as mooring cells, including the excavation of bottom material from within the form prior to the discharge of concrete, sand, rock, etc. This NWP does not authorize filled structural members that would support buildings, building pads, homes, house pads, parking areas, storage areas and other such structures. The structure itself may require a separate section 10 permit if located in navigable waters of the United States. (Authority: Section 404).

27. *Aquatic Habitat Restoration, Enhancement, and Establishment Activities.* Activities in waters of the United States associated with the restoration, enhancement, and establishment of tidal and non-tidal wetlands and riparian areas, the restoration and enhancement of non-tidal streams and other non-tidal open waters, and the rehabilitation or enhancement of tidal streams, tidal wetlands, and tidal open waters, provided those activities result in net increases in aquatic resource functions and services.

To be authorized by this NWP, the aquatic habitat restoration, enhancement, or establishment activity must be planned, designed, and implemented so that it results in aquatic habitat that resembles an ecological reference. An ecological reference may be based on the characteristics of one or more intact aquatic habitats or riparian areas of the same type that exist in the region. An ecological reference may be based on a conceptual model developed from regional ecological knowledge of the target aquatic habitat type or riparian area.

To the extent that a Corps permit is required, activities authorized by this NWP include, but are not limited to the removal of accumulated sediments; releases of sediment from reservoirs to maintain sediment transport continuity to restore downstream habitats; the installation, removal, and maintenance of small water control structures, dikes, and berms, as well as discharges of dredged or fill material to restore appropriate stream channel configurations after small water control structures, dikes, and berms are

removed; the installation of current deflectors; the enhancement, rehabilitation, or re-establishment of riffle and pool stream structure; the placement of in-stream habitat structures; modifications of the stream bed and/or banks to enhance, rehabilitate, or re-establish stream meanders; the removal of stream barriers, such as undersized culverts, fords, and grade control structures; the backfilling of artificial channels; the removal of existing drainage structures, such as drain tiles, and the filling, blocking, or reshaping of drainage ditches to restore wetland hydrology; the installation of structures or fills necessary to restore or enhance wetland or stream hydrology; the construction of small nesting islands; the construction of open water areas; the construction of oyster habitat over unvegetated bottom in tidal waters; coral restoration or relocation activities; shellfish seeding; activities needed to reestablish vegetation, including plowing or discing for seed bed preparation and the planting of appropriate wetland species; re-establishment of submerged aquatic vegetation in areas where those plant communities previously existed; re-establishment of tidal wetlands in tidal waters where those wetlands previously existed; mechanized land clearing to remove non-native invasive, exotic, or nuisance vegetation; and other related activities. Only native plant species should be planted at the site.

This NWP authorizes the relocation of non-tidal waters, including non-tidal wetlands and streams, on the project site provided there are net increases in aquatic resource functions and services.

Except for the relocation of non-tidal waters on the project site, this NWP does not authorize the conversion of a stream or natural wetlands to another aquatic habitat type (*e.g.,* the conversion of a stream to wetland or vice versa) or uplands. Changes in wetland plant communities that occur when wetland hydrology is more fully restored during wetland rehabilitation activities are not considered a conversion to another aquatic habitat type. This NWP does not authorize stream channelization. This NWP does not authorize the relocation of tidal waters or the conversion of tidal waters, including tidal wetlands, to other aquatic uses, such as the conversion of tidal wetlands into open water impoundments.

Compensatory mitigation is not required for activities authorized by this NWP since these activities must result in net increases in aquatic resource functions and services.

Reversion. For enhancement, restoration, and establishment activities conducted: (1) In accordance with the terms and conditions of a binding stream or wetland enhancement or restoration agreement, or a wetland establishment agreement, between the landowner and the U.S. Fish and Wildlife Service (FWS), the Natural Resources Conservation Service (NRCS), the Farm Service Agency (FSA), the National Marine Fisheries Service (NMFS), the National Ocean Service (NOS), U.S. Forest Service (USFS), or their designated state cooperating agencies; (2) as voluntary wetland restoration, enhancement, and establishment actions documented by the NRCS or USDA Technical Service Provider pursuant to NRCS Field Office Technical Guide standards; or (3) on reclaimed surface coal mine lands, in accordance with a Surface Mining Control and Reclamation Act permit issued by the Office of Surface Mining Reclamation and Enforcement (OSMRE) or the applicable state agency, this NWP also authorizes any future discharge of dredged or fill material associated with the reversion of the area to its documented prior condition and use (*i.e.,* prior to the restoration, enhancement, or establishment activities). The reversion must occur within five years after expiration of a limited term wetland restoration or establishment agreement or permit, and is authorized in these circumstances even if the discharge of dredged or fill material occurs after this NWP expires. The five-year reversion limit does not apply to agreements without time limits reached between the landowner and the FWS, NRCS, FSA, NMFS, NOS, USFS, or an appropriate state cooperating agency. This NWP also authorizes discharges of dredged or fill material in waters of the United States for the reversion of wetlands that were restored, enhanced, or established on prior-converted cropland or on uplands, in accordance with a binding agreement between the landowner and NRCS, FSA, FWS, or their designated state cooperating agencies (even though the restoration, enhancement, or establishment activity did not require a section 404 permit). The prior condition will be documented in the original agreement or permit, and the determination of return to prior conditions will be made by the Federal agency or appropriate state agency executing the agreement or permit. Before conducting any reversion activity, the permittee or the appropriate Federal or state agency must notify the district engineer and include the documentation of the prior condition. Once an area has reverted to its prior physical condition, it will be subject to whatever the Corps Regulatory requirements are applicable to that type of land at the time. The requirement that the activity results in a net increase in aquatic resource functions and services does not apply to reversion activities meeting the above conditions. Except for the activities described above, this NWP does not authorize any future discharge of dredged or fill material associated with the reversion of the area to its prior condition. In such cases a separate permit would be required for any reversion.

Reporting. For those activities that do not require pre-construction notification, the permittee must submit to the district engineer a copy of: (1) The binding stream enhancement or restoration agreement or wetland enhancement, restoration, or establishment agreement, or a project description, including project plans and location map; (2) the NRCS or USDA Technical Service Provider documentation for the voluntary stream enhancement or restoration action or wetland restoration, enhancement, or establishment action; or (3) the SMCRA permit issued by OSMRE or the applicable state agency. The report must also include information on baseline ecological conditions on the project site, such as a delineation of wetlands, streams, and/or other aquatic habitats. These documents must be submitted to the district engineer at least 30 days prior to commencing activities in waters of the United States authorized by this NWP.

Notification: The permittee must submit a pre-construction notification to the district engineer prior to commencing any activity (see general condition 32), except for the following activities:

(1) Activities conducted on non-Federal public lands and private lands, in accordance with the terms and conditions of a binding stream enhancement or restoration agreement or wetland enhancement, restoration, or establishment agreement between the landowner and the FWS, NRCS, FSA, NMFS, NOS, USFS or their designated state cooperating agencies;

(2) Activities conducted in accordance with the terms and conditions of a binding coral restoration or relocation agreement between the project proponent and the NMFS or any of its designated state cooperating agencies;

(3) Voluntary stream or wetland restoration or enhancement action, or wetland establishment action, documented by the NRCS or USDA Technical Service Provider pursuant to

NRCS Field Office Technical Guide standards; or

(4) The reclamation of surface coal mine lands, in accordance with an SMCRA permit issued by the OSMRE or the applicable state agency.

However, the permittee must submit a copy of the appropriate documentation to the district engineer to fulfill the reporting requirement. (Authorities: Sections 10 and 404).

Note: This NWP can be used to authorize compensatory mitigation projects, including mitigation banks and in-lieu fee projects. However, this NWP does not authorize the reversion of an area used for a compensatory mitigation project to its prior condition, since compensatory mitigation is generally intended to be permanent.

28. *Modifications of Existing Marinas.* Reconfiguration of existing docking facilities within an authorized marina area. No dredging, additional slips, dock spaces, or expansion of any kind within waters of the United States is authorized by this NWP. (Authority: Section 10).

30. *Moist Soil Management for Wildlife.* Discharges of dredged or fill material into non-tidal waters of the United States and maintenance activities that are associated with moist soil management for wildlife for the purpose of continuing ongoing, site-specific, wildlife management activities where soil manipulation is used to manage habitat and feeding areas for wildlife. Such activities include, but are not limited to, plowing or discing to impede succession, preparing seed beds, or establishing fire breaks. Sufficient riparian areas must be maintained adjacent to all open water bodies, including streams, to preclude water quality degradation due to erosion and sedimentation. This NWP does not authorize the construction of new dikes, roads, water control structures, or similar features associated with the management areas. The activity must not result in a net loss of aquatic resource functions and services. This NWP does not authorize the conversion of wetlands to uplands, impoundments, or other open water bodies. (Authority: Section 404).

Note: The repair, maintenance, or replacement of existing water control structures or the repair or maintenance of dikes may be authorized by NWP 3. Some such activities may qualify for an exemption under Section 404(f) of the Clean Water Act (see 33 CFR 323.4).

31. *Maintenance of Existing Flood Control Facilities.* Discharges of dredged or fill material resulting from activities associated with the maintenance of existing flood control facilities, including debris basins, retention/detention basins, levees, and channels that: (i) Were previously authorized by the Corps by individual permit, general permit, or 33 CFR 330.3, or did not require a permit at the time they were constructed, or (ii) were constructed by the Corps and transferred to a non-Federal sponsor for operation and maintenance. Activities authorized by this NWP are limited to those resulting from maintenance activities that are conducted within the ''maintenance baseline,'' as described in the definition below. Discharges of dredged or fill materials associated with maintenance activities in flood control facilities in any watercourse that have previously been determined to be within the maintenance baseline are authorized under this NWP. To the extent that a Corps permit is required, this NWP authorizes the removal of vegetation from levees associated with the flood control project. This NWP does not authorize the removal of sediment and associated vegetation from natural water courses except when these activities have been included in the maintenance baseline. All dredged and excavated material must be deposited and retained in an area that has no waters of the United States unless otherwise specifically approved by the district engineer under separate authorization. Proper sediment controls must be used.

Maintenance Baseline: The maintenance baseline is a description of the physical characteristics (*e.g.,* depth, width, length, location, configuration, or design flood capacity, etc.) of a flood control project within which maintenance activities are normally authorized by NWP 31, subject to any case-specific conditions required by the district engineer. The district engineer will approve the maintenance baseline based on the approved or constructed capacity of the flood control facility, whichever is smaller, including any areas where there are no constructed channels but which are part of the facility. The prospective permittee will provide documentation of the physical characteristics of the flood control facility (which will normally consist of as-built or approved drawings) and documentation of the approved and constructed design capacities of the flood control facility. If no evidence of the constructed capacity exists, the approved capacity will be used. The documentation will also include best management practices to ensure that the adverse environmental impacts caused by the maintenance activities are no more than minimal, especially in maintenance areas where there are no constructed channels. (The Corps may request maintenance records in areas where there has not been recent maintenance.) Revocation or modification of the final determination of the maintenance baseline can only be done in accordance with 33 CFR 330.5. Except in emergencies as described below, this NWP cannot be used until the district engineer approves the maintenance baseline and determines the need for mitigation and any regional or activity-specific conditions. Once determined, the maintenance baseline will remain valid for any subsequent reissuance of this NWP. This NWP does not authorize maintenance of a flood control facility that has been abandoned. A flood control facility will be considered abandoned if it has operated at a significantly reduced capacity without needed maintenance being accomplished in a timely manner. A flood control facility will not be considered abandoned if the prospective permittee is in the process of obtaining other authorizations or approvals required for maintenance activities and is experiencing delays in obtaining those authorizations or approvals.

Mitigation: The district engineer will determine any required mitigation one-time only for impacts associated with maintenance work at the same time that the maintenance baseline is approved. Such one-time mitigation will be required when necessary to ensure that adverse environmental effects are no more than minimal, both individually and cumulatively. Such mitigation will only be required once for any specific reach of a flood control project. However, if one-time mitigation is required for impacts associated with maintenance activities, the district engineer will not delay needed maintenance, provided the district engineer and the permittee establish a schedule for identification, approval, development, construction and completion of any such required mitigation. Once the one-time mitigation described above has been completed, or a determination made that mitigation is not required, no further mitigation will be required for maintenance activities within the maintenance baseline (see Note, below). In determining appropriate mitigation, the district engineer will give special consideration to natural water courses that have been included in the maintenance baseline and require mitigation and/or best management practices as appropriate.

Emergency Situations: In emergency situations, this NWP may be used to authorize maintenance activities in flood control facilities for which no maintenance baseline has been

approved. Emergency situations are those which would result in an unacceptable hazard to life, a significant loss of property, or an immediate, unforeseen, and significant economic hardship if action is not taken before a maintenance baseline can be approved. In such situations, the determination of mitigation requirements, if any, may be deferred until the emergency has been resolved. Once the emergency has ended, a maintenance baseline must be established expeditiously, and mitigation, including mitigation for maintenance conducted during the emergency, must be required as appropriate.

Notification: The permittee must submit a pre-construction notification to the district engineer before any maintenance work is conducted (see general condition 32). The pre-construction notification may be for activity-specific maintenance or for maintenance of the entire flood control facility by submitting a five-year (or less) maintenance plan. The pre-construction notification must include a description of the maintenance baseline and the disposal site for dredged or excavated material. (Authorities: Sections 10 and 404)

Note: If the maintenance baseline was approved by the district engineer under a prior version of NWP 31, and the district engineer imposed the one-time compensatory mitigation requirement on maintenance for a specific reach of a flood control project authorized by that prior version of NWP 31, during the period this version of NWP 31 is in effect, the district engineer will not require additional compensatory mitigation for maintenance activities authorized by this NWP in that specific reach of the flood control project.

32. *Completed Enforcement Actions.* Any structure, work, or discharge of dredged or fill material remaining in place or undertaken for mitigation, restoration, or environmental benefit in compliance with either:

(i) The terms of a final written Corps non-judicial settlement agreement resolving a violation of Section 404 of the Clean Water Act and/or Section 10 of the Rivers and Harbors Act of 1899; or the terms of an EPA 309(a) order on consent resolving a violation of Section 404 of the Clean Water Act, provided that:

(a) The activities authorized by this NWP cannot adversely affect more than 5 acres of non-tidal waters or 1 acre of tidal waters;

(b) The settlement agreement provides for environmental benefits, to an equal or greater degree, than the environmental detriments caused by the unauthorized activity that is authorized by this NWP; and

(c) The district engineer issues a verification letter authorizing the activity subject to the terms and conditions of this NWP and the settlement agreement, including a specified completion date; or

(ii) The terms of a final Federal court decision, consent decree, or settlement agreement resulting from an enforcement action brought by the United States under Section 404 of the Clean Water Act and/or Section 10 of the Rivers and Harbors Act of 1899; or

(iii) The terms of a final court decision, consent decree, settlement agreement, or non-judicial settlement agreement resulting from a natural resource damage claim brought by a trustee or trustees for natural resources (as defined by the National Contingency Plan at 40 CFR subpart G) under Section 311 of the Clean Water Act, Section 107 of the Comprehensive Environmental Response, Compensation and Liability Act, Section 312 of the National Marine Sanctuaries Act, Section 1002 of the Oil Pollution Act of 1990, or the Park System Resource Protection Act at 16 U.S.C. 19jj, to the extent that a Corps permit is required.

Compliance is a condition of the NWP itself; non-compliance of the terms and conditions of an NWP 32 authorization may result in an additional enforcement action (*e.g.,* a Class I civil administrative penalty). Any authorization under this NWP is automatically revoked if the permittee does not comply with the terms of this NWP or the terms of the court decision, consent decree, or judicial/non-judicial settlement agreement. This NWP does not apply to any activities occurring after the date of the decision, decree, or agreement that are not for the purpose of mitigation, restoration, or environmental benefit. Before reaching any settlement agreement, the Corps will ensure compliance with the provisions of 33 CFR part 326 and 33 CFR 330.6(d)(2) and (e). (Authorities: Sections 10 and 404)

33. *Temporary Construction, Access, and Dewatering.* Temporary structures, work, and discharges of dredged or fill material, including cofferdams, necessary for construction activities or access fills or dewatering of construction sites, provided that the associated primary activity is authorized by the Corps of Engineers or the U.S. Coast Guard. This NWP also authorizes temporary structures, work, and discharges of dredged or fill material, including cofferdams, necessary for construction activities not otherwise subject to the Corps or U.S. Coast Guard permit requirements. Appropriate measures must be taken to maintain near normal downstream flows and to minimize flooding. Fill must consist of materials, and be placed in a manner, that will not be eroded by expected high flows. The use of dredged material may be allowed if the district engineer determines that it will not cause more than minimal adverse environmental effects. Following completion of construction, temporary fill must be entirely removed to an area that has no waters of the United States, dredged material must be returned to its original location, and the affected areas must be restored to pre-construction elevations. The affected areas must also be revegetated, as appropriate. This permit does not authorize the use of cofferdams to dewater wetlands or other aquatic areas to change their use. Structures left in place after construction is completed require a separate section 10 permit if located in navigable waters of the United States. (See 33 CFR part 322.)

Notification: The permittee must submit a pre-construction notification to the district engineer prior to commencing the activity if the activity is conducted in navigable waters of the United States (*i.e.,* section 10 waters) (see general condition 32). The pre-construction notification must include a restoration plan showing how all temporary fills and structures will be removed and the area restored to pre-project conditions. (Authorities: Sections 10 and 404)

34. *Cranberry Production Activities.* Discharges of dredged or fill material for dikes, berms, pumps, water control structures or leveling of cranberry beds associated with expansion, enhancement, or modification activities at existing cranberry production operations. The cumulative total acreage of disturbance per cranberry production operation, including but not limited to, filling, flooding, ditching, or clearing, must not exceed 10 acres of waters of the United States, including wetlands. The activity must not result in a net loss of wetland acreage. This NWP does not authorize any discharge of dredged or fill material related to other cranberry production activities such as warehouses, processing facilities, or parking areas. For the purposes of this NWP, the cumulative total of 10 acres will be measured over the period that this NWP is valid.

Notification: The permittee must submit a pre-construction notification to the district engineer once during the period that this NWP is valid, and the NWP will then authorize discharges of dredge or fill material at an existing operation for the permit term, provided

the 10-acre limit is not exceeded. (See general condition 32.) (Authority: Section 404)

35. *Maintenance Dredging of Existing Basins.* The removal of accumulated sediment for maintenance of existing marina basins, access channels to marinas or boat slips, and boat slips to previously authorized depths or controlling depths for ingress/egress, whichever is less. All dredged material must be deposited and retained in an area that has no waters of the United States unless otherwise specifically approved by the district engineer under separate authorization. Proper sediment controls must be used for the disposal site. (Authority: Section 10)

36. *Boat Ramps.* Activities required for the construction, repair, or replacement of boat ramps, provided the activity meets all of the following criteria:

(a) The discharge of dredged or fill material into waters of the United States does not exceed 50 cubic yards of concrete, rock, crushed stone or gravel into forms, or in the form of pre-cast concrete planks or slabs, unless the district engineer waives the 50 cubic yard limit by making a written determination concluding that the discharge of dredged or fill material will result in no more than minimal adverse environmental effects;

(b) The boat ramp does not exceed 20 feet in width, unless the district engineer waives this criterion by making a written determination concluding that the discharge of dredged or fill material will result in no more than minimal adverse environmental effects;

(c) The base material is crushed stone, gravel or other suitable material;

(d) The excavation is limited to the area necessary for site preparation and all excavated material is removed to an area that has no waters of the United States; and,

(e) No material is placed in special aquatic sites, including wetlands.

The use of unsuitable material that is structurally unstable is not authorized. If dredging in navigable waters of the United States is necessary to provide access to the boat ramp, the dredging must be authorized by another NWP, a regional general permit, or an individual permit.

Notification: The permittee must submit a pre-construction notification to the district engineer prior to commencing the activity if: (1) The discharge of dredged or fill material into waters of the United States exceeds 50 cubic yards, or (2) the boat ramp exceeds 20 feet in width. (See general condition 32.) (Authorities: Sections 10 and 404)

37. *Emergency Watershed Protection and Rehabilitation.* Work done by or funded by:

(a) The Natural Resources Conservation Service for a situation requiring immediate action under its emergency Watershed Protection Program (7 CFR part 624);

(b) The U.S. Forest Service under its Burned-Area Emergency Rehabilitation Handbook (FSH 2509.13);

(c) The Department of the Interior for wildland fire management burned area emergency stabilization and rehabilitation (DOI Manual part 620, Ch. 3);

(d) The Office of Surface Mining, or states with approved programs, for abandoned mine land reclamation activities under Title IV of the Surface Mining Control and Reclamation Act (30 CFR subchapter R), where the activity does not involve coal extraction; or

(e) The Farm Service Agency under its Emergency Conservation Program (7 CFR part 701).

In general, the permittee should wait until the district engineer issues an NWP verification or 45 calendar days have passed before proceeding with the watershed protection and rehabilitation activity. However, in cases where there is an unacceptable hazard to life or a significant loss of property or economic hardship will occur, the emergency watershed protection and rehabilitation activity may proceed immediately and the district engineer will consider the information in the pre-construction notification and any comments received as a result of agency coordination to decide whether the NWP 37 authorization should be modified, suspended, or revoked in accordance with the procedures at 33 CFR 330.5.

Notification: Except in cases where there is an unacceptable hazard to life or a significant loss of property or economic hardship will occur, the permittee must submit a pre-construction notification to the district engineer prior to commencing the activity (see general condition 32). (Authorities: Sections 10 and 404)

38. *Cleanup of Hazardous and Toxic Waste.* Specific activities required to effect the containment, stabilization, or removal of hazardous or toxic waste materials that are performed, ordered, or sponsored by a government agency with established legal or regulatory authority. Court ordered remedial action plans or related settlements are also authorized by this NWP. This NWP does not authorize the establishment of new disposal sites or the expansion of existing sites used for the disposal of hazardous or toxic waste.

Notification: The permittee must submit a pre-construction notification to the district engineer prior to commencing the activity. (See general condition 32.) (Authorities: Sections 10 and 404)

Note: Activities undertaken entirely on a Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) site by authority of CERCLA as approved or required by EPA, are not required to obtain permits under Section 404 of the Clean Water Act or Section 10 of the Rivers and Harbors Act.

41. *Reshaping Existing Drainage and Irrigation Ditches.* Discharges of dredged or fill material into non-tidal waters of the United States, excluding non-tidal wetlands adjacent to tidal waters, to modify the cross-sectional configuration of currently serviceable drainage and irrigation ditches constructed in waters of the United States, for the purpose of improving water quality by regrading the drainage or irrigation ditch with gentler slopes, which can reduce erosion, increase growth of vegetation, and increase uptake of nutrients and other substances by vegetation. The reshaping of the drainage ditch cannot increase drainage capacity beyond the original as-built capacity nor can it expand the area drained by the drainage ditch as originally constructed (*i.e.,* the capacity of the drainage ditch must be the same as originally constructed and it cannot drain additional wetlands or other waters of the United States). Compensatory mitigation is not required because the work is designed to improve water quality.

This NWP does not authorize the relocation of drainage or irrigation ditches constructed in waters of the United States; the location of the centerline of the reshaped drainage or irrigation ditch must be approximately the same as the location of the centerline of the original drainage or irrigation ditch. This NWP does not authorize stream channelization or stream relocation projects. (Authority: Section 404)

45. *Repair of Uplands Damaged by Discrete Events.* This NWP authorizes discharges of dredged or fill material, including dredging or excavation, into all waters of the United States for activities associated with the restoration of upland areas damaged by storms, floods, or other discrete events. This NWP authorizes bank stabilization to protect the restored uplands. The restoration of the damaged areas, including any bank stabilization, must not exceed the contours, or ordinary high water mark, that existed before the damage occurred. The district engineer

retains the right to determine the extent of the pre-existing conditions and the extent of any restoration work authorized by this NWP. The work must commence, or be under contract to commence, within two years of the date of damage, unless this condition is waived in writing by the district engineer. This NWP cannot be used to reclaim lands lost to normal erosion processes over an extended period.

This NWP does not authorize beach restoration or nourishment.

Minor dredging is limited to the amount necessary to restore the damaged upland area and should not significantly alter the pre-existing bottom contours of the waterbody.

Notification: The permittee must submit a pre-construction notification to the district engineer (see general condition 32) within 12 months of the date of the damage; for major storms, floods, or other discrete events, the district engineer may waive the 12-month limit for submitting a pre-construction notification if the permittee can demonstrate funding, contract, or other similar delays. The pre-construction notification must include documentation, such as a recent topographic survey or photographs, to justify the extent of the proposed restoration. (Authorities: Sections 10 and 404)

Note: The uplands themselves that are lost as a result of a storm, flood, or other discrete event can be replaced without a Clean Water Act Section 404 permit, if the uplands are restored to the ordinary high water mark (in non-tidal waters) or high tide line (in tidal waters). (See also 33 CFR 328.5.) This NWP authorizes discharges of dredged or fill material into waters of the United States associated with the restoration of uplands.

46. *Discharges in Ditches.* Discharges of dredged or fill material into non-tidal ditches that are (1) constructed in uplands, (2) receive water from an area determined to be a water of the United States prior to the construction of the ditch, (3) divert water to an area determined to be a water of the United States prior to the construction of the ditch, and (4) determined to be waters of the United States. The discharge of dredged or fill material must not cause the loss of greater than one acre of waters of the United States.

This NWP does not authorize discharges of dredged or fill material into ditches constructed in streams or other waters of the United States, or in streams that have been relocated in uplands. This NWP does not authorize discharges of dredged or fill material that increase the capacity of the ditch and drain those areas determined to be waters of the United States prior to construction of the ditch.

Notification: The permittee must submit a pre-construction notification to the district engineer prior to commencing the activity. (See general condition 32.) (Authority: Section 404)

49. *Coal Remining Activities.* Discharges of dredged or fill material into non-tidal waters of the United States associated with the remining and reclamation of lands that were previously mined for coal. The activities must already be authorized, or they must currently be in process by the Department of the Interior Office of Surface Mining Reclamation and Enforcement, or by states with approved programs under Title IV or Title V of the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Areas previously mined include reclaimed mine sites, abandoned mine land areas, or lands under bond forfeiture contracts.

As part of the project, the permittee may conduct new coal mining activities in conjunction with the remining activities when he or she clearly demonstrates to the district engineer that the overall mining plan will result in a net increase in aquatic resource functions. The Corps will consider the SMCRA agency's decision regarding the amount of currently undisturbed adjacent lands needed to facilitate the remining and reclamation of the previously mined area. The total area disturbed by new mining must not exceed 40 percent of the total acreage covered by both the remined area and the additional area necessary to carry out the reclamation of the previously mined area.

Notification: The permittee must submit a pre-construction notification and a document describing how the overall mining plan will result in a net increase in aquatic resource functions to the district engineer and receive written authorization prior to commencing the activity. (See general condition 32.) (Authorities: Sections 10 and 404)

53. *Removal of Low-Head Dams.* Structures and work in navigable waters of the United States and discharges of dredged or fill material into waters of the United States associated with the removal of low-head dams.

For the purposes of this NWP, the term ''low-head dam'' is generally defined as a dam or weir built across a stream to pass flows from upstream over all, or nearly all, of the width of the dam crest and does not have a separate spillway or spillway gates, but it may have an uncontrolled spillway. The dam crest is the top of the dam from left abutment to right abutment. A low-head dam may have been built for a range of purposes (*e.g.,* check dam, mill dam, irrigation, water supply, recreation, hydroelectric, or cooling pond), but in all cases, it provides little or no storage function.

The removed low-head dam structure must be deposited and retained in an area that has no waters of the United States unless otherwise specifically approved by the district engineer under separate authorization.

Because the removal of the low-head dam will result in a net increase in ecological functions and services provided by the stream, as a general rule compensatory mitigation is not required for activities authorized by this NWP. However, the district engineer may determine for a particular low-head dam removal activity that compensatory mitigation is necessary to ensure that the authorized activity results in no more than minimal adverse environmental effects.

Notification: The permittee must submit a pre-construction notification to the district engineer prior to commencing the activity. (See general condition 32.) (Authorities: Sections 10 and 404)

Note: This NWP does not authorize discharges of dredged or fill material into waters of the United States or structures or work in navigable waters to restore the stream in the vicinity of the low-head dam, including the former impoundment area. Nationwide permit 27 or other Department of the Army permits may authorize such activities. This NWP does not authorize discharges of dredged or fill material into waters of the United States or structures or work in navigable waters to stabilize stream banks. Bank stabilization activities may be authorized by NWP 13 or other Department of the Army permits.

54. *Living Shorelines.* Structures and work in navigable waters of the United States and discharges of dredged or fill material into waters of the United States for the construction and maintenance of living shorelines to stabilize banks and shores in coastal waters, which includes the Great Lakes, along shores with small fetch and gentle slopes that are subject to low- to mid-energy waves. A living shoreline has a footprint that is made up mostly of native material. It incorporates vegetation or other living, natural ''soft'' elements alone or in combination with some type of harder shoreline structure (*e.g.,* oyster or mussel reefs or rock sills) for added protection and stability. Living shorelines should maintain the natural continuity of the land-water interface, and retain or enhance shoreline ecological processes. Living

shorelines must have a substantial biological component, either tidal or lacustrine fringe wetlands or oyster or mussel reef structures. The following conditions must be met:

(a) The structures and fill area, including sand fills, sills, breakwaters, or reefs, cannot extend into the waterbody more than 30 feet from the mean low water line in tidal waters or the ordinary high water mark in the Great Lakes, unless the district engineer waives this criterion by making a written determination concluding that the activity will result in no more than minimal adverse environmental effects;

(b) The activity is no more than 500 feet in length along the bank, unless the district engineer waives this criterion by making a written determination concluding that the activity will result in no more than minimal adverse environmental effects;

(c) Coir logs, coir mats, stone, native oyster shell, native wood debris, and other structural materials must be adequately anchored, of sufficient weight, or installed in a manner that prevents relocation in most wave action or water flow conditions, except for extremely severe storms;

(d) For living shorelines consisting of tidal or lacustrine fringe wetlands, native plants appropriate for current site conditions, including salinity and elevation, must be used if the site is planted by the permittee;

(e) Discharges of dredged or fill material into waters of the United States, and oyster or mussel reef structures in navigable waters, must be the minimum necessary for the establishment and maintenance of the living shoreline;

(f) If sills, breakwaters, or other structures must be constructed to protect fringe wetlands for the living shoreline, those structures must be the minimum size necessary to protect those fringe wetlands;

(g) The activity must be designed, constructed, and maintained so that it has no more than minimal adverse effects on water movement between the waterbody and the shore and the movement of aquatic organisms between the waterbody and the shore; and

(h) The living shoreline must be properly maintained, which may require periodic repair of sills, breakwaters, or reefs, or replacing sand fills after severe storms or erosion events. Vegetation may be replanted to maintain the living shoreline. This NWP authorizes those maintenance and repair activities, including any minor deviations necessary to address changing environmental conditions.

This NWP does not authorize beach nourishment or land reclamation activities.

Notification: The permittee must submit a pre-construction notification to the district engineer prior to commencing the construction of the living shoreline. (See general condition 32.) The pre-construction notification must include a delineation of special aquatic sites (see paragraph (b)(4) of general condition 32). Pre-construction notification is not required for maintenance and repair activities for living shorelines unless required by applicable NWP general conditions or regional conditions. (Authorities: Sections 10 and 404)

Note: In waters outside of coastal waters, nature-based bank stabilization techniques, such as bioengineering and vegetative stabilization, may be authorized by NWP 13.

59. *Water reclamation and reuse facilities.* Discharges of dredged or fill material into non-tidal waters of the United States for the construction, expansion, and maintenance of water reclamation and reuse facilities, including vegetated areas enhanced to improve water infiltration and constructed wetlands to improve water quality.

The discharge of dredged or fill material must not cause the loss of greater than 1/2-acre of waters of the United States. This NWP does not authorize discharges of dredged or fill material into non-tidal wetlands adjacent to tidal waters.

This NWP also authorizes temporary fills, including the use of temporary mats, necessary to construct the water reuse project and attendant features. Appropriate measures must be taken to maintain normal downstream flows and minimize flooding to the maximum extent practicable, when temporary structures, work, and discharges of dredged or fill material, including cofferdams, are necessary for construction activities, access fills, or dewatering of construction sites. Temporary fills must consist of materials, and be placed in a manner, that will not be eroded by expected high flows. After construction, temporary fills must be removed in their entirety and the affected areas returned to pre-construction elevations. The areas affected by temporary fills must be revegetated, as appropriate.

Notification: The permittee must submit a pre-construction notification to the district engineer prior to commencing the activity. (See general condition 32.) (Authorities: Sections 10 and 404)

C. Nationwide Permit General Conditions

See the final rule published in the January 13, 2021, issue of the **Federal Register** at 86 FR 2867–2874 for the text of section C, General Conditions:

1. Navigation
2. Aquatic Life Movements
3. Spawning Areas
4. Migratory Bird Breeding Areas
5. Shellfish Beds
6. Suitable Material
7. Water Supply Intakes
8. Adverse Effects from Impoundments
9. Management of Water Flows
10. Fills Within 100-Year Floodplains
11. Equipment
12. Soil Erosion and Sediment Controls
13. Removal of Temporary Fills
14. Proper Maintenance
15. Single and Complete Project
16. Wild and Scenic Rivers
17. Tribal Rights
18. Endangered Species
19. Migratory Birds and Bald and Golden Eagles
20. Historic Properties
21. Discovery of Previously Unknown Remains and Artifacts
22. Designated Critical Resource Waters
23. Mitigation
24. Safety of Impoundment Structures
25. Water Quality
26. Coastal Zone Management
27. Regional and Case-by-Case Conditions
28. Use of Multiple Nationwide Permits
29. Transfer of Nationwide Permit Verifications
30. Compliance Certification
31. Activities Affecting Structures or Works Built by the United States
32. Pre-Construction Notification

D. District Engineer's Decision

See the final rule published in the January 13, 2021, issue of the **Federal Register** at 86 FR 2874–2875 for the text of section D, District Engineer's Decision:

E. Further Information

See the final rule published in the January 13, 2021, issue of the **Federal Register** at 86 FR 2875 for the text of section E, Further Information.

F. Definitions

See the final rule published in the January 13, 2021, issue of the **Federal Register** at 86 FR 2875–2877 for the text of section F, Definitions:

Best management practices (BMPs)
Compensatory mitigation
Currently serviceable
Direct effects
Discharge
Ecological reference

Enhancement
Establishment (creation)
High Tide Line
Historic property
Independent utility
Indirect effects
Loss of waters of the United States
Navigable waters
Non-tidal wetland
Open water
Ordinary high water mark
Perennial stream
Practicable
Pre-construction notification
Preservation
Re-establishment
Rehabilitation
Restoration
Riffle and pool complex
Riparian areas
Shellfish seeding
Single and complete linear project
Single and complete non-linear project
Stormwater management
Stormwater management facilities
Stream bed
Stream channelization
Structure
Tidal wetland
Tribal lands
Tribal rights
Vegetated shallows
Waterbody

[FR Doc. 2021–27441 Filed 12–23–21; 8:45 am]
BILLING CODE 3720–58–P

FEDERAL REGISTER

Vol. 86 Monday,
No. 245 December 27, 2021

Part IV

The President

Federal Register
Vol. 86, No. 245
Monday, December 27, 2021

Presidential Documents

Title 3—

The President

Presidential Determination No. 2022–07 of December 21, 2021

Presidential Determination Pursuant to Section 303 of the Defense Production Act of 1950, as Amended

Memorandum for the Secretary of Defense

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 303 of the Defense Production Act of 1950, as amended (the ''Act'') (50 U.S.C. 4533), I hereby determine, pursuant to section 303(a)(5) of the Act, that:

(1) Large Scale Fabrication, Shipbuilding Industrial Base Expansion for Resilience and Robustness, and Maritime Workforce Training Pipelines in support of Virginia Class attack submarine production are industrial resources, materials, or critical technology items essential to the national defense;

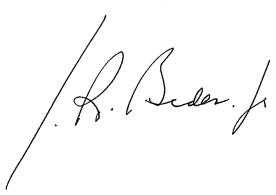
(2) without Presidential action under section 303 of the Act, United States industry cannot reasonably be expected to provide the capability for the needed industrial resource, material, or critical technology item in a timely manner; and

(3) purchases, purchase commitments, or other action pursuant to section 303 of the Act are the most cost-effective, expedient, and practical alternative method for meeting the need.

Pursuant to section 303(a)(7)(B) of the Act, I find that action to expand the domestic production capability for these supply chains is necessary to avert an industrial resource or critical technology item shortfall that would severely impair national defense capability. Therefore, I waive the requirements of section 303(a)(l)–(a)(6) of the Act for the purpose of expanding the domestic production capability for these supply chains.

Ensuring a robust, resilient, and competitive domestic defense industrial base that has the capability, capacity, and workforce to meet the Virginia Class submarine undersea warfighting mission is essential to our national security.

You are authorized and directed to publish this determination in the *Federal Register*.



THE WHITE HOUSE,
Washington, December 21, 2021

[FR Doc. 2021–28284
Filed 12–23–21; 11:15 am]
Billing code 5001–06–P

Presidential Documents

Presidential Determination No. 2022–08 of December 21, 2021

Presidential Determination Pursuant to Section 303 of the Defense Production Act of 1950, as Amended

Memorandum for the Secretary of Defense

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 303 of the Defense Production Act of 1950, as amended (the ''Act'') (50 U.S.C. 4533), I hereby determine, pursuant to section 303(a)(5) of the Act, that:

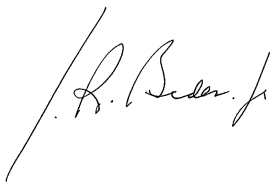
(1) Radiation-Hardened and Strategic Radiation-Hardened Microelectronics, their components, and the manufacturing systems to produce such systems and components are industrial resources, materials, or critical technology items essential to the national defense;

(2) without Presidential action under section 303 of the Act, United States industry cannot reasonably be expected to provide the capability for the needed industrial resource, material, or critical technology item in a timely manner; and

(3) purchases, purchase commitments, or other action pursuant to section 303 of the Act are the most cost-effective, expedient, and practical alternative method for meeting the need.

Pursuant to section 303(a)(7)(B) of the Act, I find that action to expand the domestic production capability for Radiation-Hardened and Strategic Radiation-Hardened Microelectronics is necessary to avert an industrial resource or critical technology item shortfall that would severely impair national defense capability. Therefore, I waive the requirements of section 303(a)(l)–(a)(6) of the Act for the purpose of expanding the domestic production capability for these supply chains.

You are authorized and directed to publish this determination in the *Federal Register*.



THE WHITE HOUSE,
Washington, December 21, 2021

[FR Doc. 2021–28285
Filed 12–23–21; 11:15 am]
Billing code 5001–06–P

Reader Aids

Federal Register

Vol. 86, No. 245

Monday, December 27, 2021

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6050**

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, DECEMBER

68103–68388 1
68389–68532 2
68533–68874 3
68875–69156 6
69157–69574 7
69575–69974 8
69975–70348 9
70349–70688 10
70689–70944 13
70945–71126 14
71127–71354 15
71355–71548 16
71549–71792 17
71793–72144 20
72145–72506 21
72507–72778 22
72779–73104 23
73105–73590 27

CFR PARTS AFFECTED DURING DECEMBER

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.

2 CFR

200 68533

3 CFR

Proclamations:
10314 68103
10315 68385
10316 68867
10317 68869
10318 69157
10319 69575
10320 69975
10320, (amended by 10322) 71355
10321 71127
10322 71355
10324 72505

Executive Orders:
13803 (Superseded and revoked by EO 14056) 68871
13906 (Superseded and revoked by EO 14056) 68871
14056 68871
14057 70935
14058 71357
14059 71549
14060 71793

Administrative Orders:
Presidential Determinations:
Presidential Determination No. 2022–07 of December 21, 2021 73587
Presidential Determination No. 2022–08 of December 21, 2021 73589

6 CFR

5 69977

Proposed Rules:
5 69587

7 CFR

756 70689
760 70689
915 69159
930 72145
1216 72148
1218 72779
1280 72507
1410 70689
1421 70689
1425 70689
1427 70689
1430 70689
1434 70689
1435 70689
1471 68875
1484 68880
1485 68882
4274 72151
5001 70349

Proposed Rules:
457 71396
983 68932
986 68934

8 CFR

214 72516
1001 70708
1003 70708
1103 70708
1208 70708
1240 70708
1245 70708
1246 70708
1292 70708

9 CFR

2 68533
92 68834
93 68834
94 68834
95 68834
96 68834
98 68834

Proposed Rules:
11 70755

10 CFR

72 ..... 69978, 71129
429 68389
430 ..... 68389, 70892, 70945, 71797
431 70945

Proposed Rules:
53 70423
72 ..... 70056, 70059, 70060
429 ..... 69544, 70316, 70644, 71710, 72096, 72322, 72874
430 ..... 69544, 70755, 71406, 72738
431 ..... 70316, 70644, 71710, 71840, 72096, 72322, 72874

11 CFR

1 72874
104 72874
110 72874

12 CFR

25 71328
43 71810
204 69577
209 69578
228 71813
244 71810
345 71813

373.....71810
614.....68395
615.....68395
620.....68395
628.....68395
701.....72517
702.....72784, 72807
703.....72784, 72810
721.....72810
741.....72807
1003.....72818
1026.....69716, 72820
1234.....71810

Proposed Rules:

1002.....70771
1240.....73187

14 CFR

39 .....68105, 68107, 68109, 68884, 68887, 68889, 68892, 68894, 68897, 68899, 68902, 68905. 68907, 68910, 69161, 69163, 69165, 69579, 69984, 69987, 69990, 69992, 69996, 69998, 70000, 70358, 70361, 70364, 70367, 70725, 70962, 70964, 70966, 70969, 70972, 71129, 71131, 71134, 71135, 71367, 71370, 71555, 71815, 71818, 71820, 71823, 71825, 72171, 72174, 72178, 72181, 72183, 72186, 72824, 72827, 72829, 72833, 72836, 72838, 72840
71 .....68395, 68538, 68912, 69581, 70368, 70370
91.....69167
97 .....68539, 68541, 71138, 71139
107.....71109, 71372

Proposed Rules:

25.....71183
39 .....68166, 68168, 68171, 68937, 70987, 71587, 71589, 71592, 71594, 72195, 72198, 72891, 72895, 73194, 73197
71 .....68173, 68571, 69181, 70057, 70059, 70060, 70423, 70425, 70771, 70773, 70774, 70776, 70778, 70780, 70783, 70785, 70989, 70991, 70992, 71186, 71409, 71411, 71597, 71600, 71601, 72897, 73200, 73202, 73203, 73205

15 CFR

705.....70003
740.....70015
742.....70015
744.....70015, 71557

Proposed Rules:

7.....72900
30.....71187

16 CFR

306.....69582
313.....70020
314.....70272

Proposed Rules:

1 .....70062, 73206, 73207
314.....70062
461.....72901

17 CFR

200.....70027
202.....70166
211.....68111
229.....70166
230.....70166
232.....70027, 70166
239.....70166
240.....68330, 70166
246.....71810
249.....70027
270.....70166
274.....70166

Proposed Rules:

240.....68300, 69802

19 CFR

12.....68544, 68546
Ch. I.....72842, 72843
356.....70045

20 CFR

404.....70728
655.....70729, 71373
656.....70729

Proposed Rules:

655.....68174

21 CFR

1.....68728
11.....68728
16.....68728
129.....68728
868.....68396
876 .....68398, 70371, 70733, 71142, 71144
878.....70373, 71568
882 .....68399, 68401, 70375, 70731, 71383
888.....68403
890.....69583
1141.....70052

Proposed Rules:

112.....69120
888.....71191, 71197
1308.....69182, 69187

22 CFR

42.....70735
51.....72520
126.....70053

23 CFR

645.....68553

24 CFR

267.....71810

25 CFR

15.....72068

Proposed Rules:

514.....68445
522.....70067
537.....68446
559.....68200

26 CFR

Proposed Rules:

1.....68939
301.....68939

27 CFR

Proposed Rules:

1.....68573
17.....68573
19.....68573
20.....68573
22.....68573
26.....68573
27.....68573
28.....68573
31.....68573

28 CFR

2.....71828
72.....69856
85.....70740

Proposed Rules:

5.....70787

29 CFR

10.....71829
531.....71829
1910.....68560, 69583
1915.....68560, 69583
1917.....68560, 69583
1918.....68560, 69583
1926.....68560, 69583
1928.....68560, 69583
4044.....68560, 71146

Proposed Rules:

1910.....68594
1915.....68594
1917.....68594
1918.....68594
1926.....68594
1928.....68594

30 CFR

Proposed Rules:

56.....71860
57.....71860
77.....71860

31 CFR

539.....73105
1010.....72844

Proposed Rules:

Ch. X 69589, 71201
1010.....69920

32 CFR

233.....70746
242.....70748
310.....72523
Ch. VII.....71570

Proposed Rules:

310.....72536

33 CFR

100.....68405
135.....68123
138.....68123
153.....68123
165 .....68406, 68407, 68562, 68564, 68566, 68913, 70377, 70378, 70380, 70749, 70975, 71146, 71570, 71573, 72188
Ch. II.....73522

Proposed Rules:

100.....69602, 71412
165.....68948
328.....69372

34 CFR

75.....70612

Proposed Rules:

Ch. II.....71207
Ch. VI.....69607

36 CFR

7.....71148
219.....68149

Proposed Rules:

251.....72540

37 CFR

380.....68150
387.....72845

Proposed Rules:

1.....69195, 71209
201.....69890
220.....69890
222.....69890
225.....69890
226.....69890
227.....69890
228.....69890
229.....69890
230.....69890
231.....69890
232.....69890
233.....69890

38 CFR

3.....68409

39 CFR

20.....70977
111.....70382

Proposed Rules:

3065.....68202

40 CFR

9.....70385
52 .....68411, 68413, 68421, 68568, 69173, 70409, 71385, 71830, 73106, 73129
141.....71574, 73131
171.....71831
180 .....68150, 68915, 68918, 68921, 70978, 70980, 71152, 71155, 71158, 71388, 72190, 72525, 72846
272.....68159
721.....70385

Proposed Rules:

52 .....68447, 68449, 68954, 68957, 68960, 69198, 69200, 69207, 69210, 70070, 70994, 70996, 71213, 71214, 72906
60.....71603
63.....73207
80 .....70426, 70999, 72436
82.....68962
120.....69372
171.....71000
174.....72200
180.....72200
271.....70790
761.....71862
1090.....70426, 72436

41 CFR

Proposed Rules:

102–73.....71604

42 CFR

100.....68423
403.....73157
405.....73157
409.....72531
410.....73157
411.....73157
412.....73416
413.....70982, 73416
414.....73157

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. This list is also available online at *https://www.archives.gov/federal-register/laws*.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available at *https://www.govinfo.gov*. Some laws may not yet be available.

S. 3377/P.L. 117–77
Capitol Police Emergency Assistance Act of 2021 (Dec. 22, 2021; 135 Stat. 1522)

H.R. 6256/P.L. 117–78
To ensure that goods made with forced labor in the Xinjiang Uyghur Autonomous Region of the People's Republic of China do not enter the United States market, and for other purposes. (Dec. 23, 2021; 135 Stat. 1525)

Last List December 22, 2021

Public Laws Electronic Notification Service (PENS)

PENS is a free email notification service of newly enacted public laws. To subscribe, go to *https://listserv.gsa.gov/cgi-bin/wa.exe?SUBED1=PUBLAWS-L&A=1*

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.